IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DAWN GRAY,	)	
	)	2:23-cv-00263-KNS
Plaintiff	)	
	)	**PLAINTIFF'S APPENDIX**
v.	)	**IN OPPOSITION TO**
	)	**MOTION FOR SUMMARY**
MAIN LINE HOSPITALS, INC.	)	**JUDGEMENT**
Defendant	)	
	)	

Dated: October 30, 2023

Respectfully submitted,

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EXHIBIT A

BACKGROUND

My curriculum vitae, appended to this report, demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years. Below, I summarize the relevant highlights of my education, training, and experience that qualify me to render opinions in this matter. I am not receiving compensation for my review of this matter as I am offering my services *pro bono*, with the exception of any expenses that may be incurred for traveling for deposition or trial if needed.

After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a Master's degree in Public Health in the field of epidemiology at The University of Michigan.

I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology (and previously echocardiography). I participate in the maintenance of certification programs by the American Board of Internal Medicine for both Internal Medicine and Cardiovascular Diseases. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with current and previous roles as an author and editor-in-chief of one peer-reviewed journal as well as editorialist and reviewer at dozens of major medical journals and textbooks.

I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of in

vitro natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of antidiabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of more than 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies and the National Institutes of Health.

I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have extensively published my research on subjects in addition to COVID-19, having more than 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook, and over 680 citations in the National Library of Medicine. My works have appeared in the *New England Journal of Medicine*, the *Journal of the American Medical Association*, *Lancet*, the *British Medical Journal* and other top-tier journals worldwide.

I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology. I am the former editor-in-chief of *Reviews in Cardiovascular Medicine* and *Cardiorenal Medicine*, and the former senior associate editor of the *American Journal of Cardiology*.

In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am a founding member of Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engaging in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, The New Hampshire Senate, the Colorado House of Commons, the Texas Senate Committee on Health and Human Services and the South Carolina Senate.

Specifically, On November 19, 2020, I testified before the US Senate Committee on Homeland Security and Governmental Affairs concerning early ambulatory treatment of high-risk patients with COVID-19. On January 24, 2022, I co-moderated and testified at the US Senate Panel "COVID-19: A Second Opinion" led by Senator Ron Johnson. Subsequently, on December 7, 2022, I co-moderated the US Senate Panel "COVID-19 Vaccines, How do They Work, and How are They Causing Injuries, Disabilities, and death.

[1] http://www.cardiorenalsociety.org/

During 2021-2022, I have testified in the following state senates on pandemic response: Arizona, Colorado (House of Commons), Idaho (District Health Board of Health, County Commissioners Meetings), Mississippi, New Hampshire, Pennsylvania, Texas, South Carolina. On September 13, 2023, I testified in the European Parliament and after presentation of safey data, I called for all COVID-19 vaccines and future boosters to be removed from the Euopean market.

Since the outset of the COVID-19 pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the American Journal of Medicine and (updated in Reviews in Cardiovascular Medicine).[2] I have over 50 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of op-eds for The Hill in 2020. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified at the Texas Senate Committee on Health and Human Services on March 10, 2021, on lessons learned from the pandemic response, and on early treatment of COVID-19 at the Colorado

[2] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh, B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high- risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517 doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/.

General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. I have also testified before the South Carolina Senate Medical Advisory Committee on the treatment of COVID-19.

My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, was approximately 20 months old with the review of hundreds of manuscripts and with the care of many patients with acute COVID-19, post-COVID-19 long-hauler syndromes, and COVID-19 vaccine injury syndromes including neurologic damage, myocarditis, and a variety of other internal medicine problems that have occurred after the mRNA and adenoviral DNA COVID-19 vaccines at the relevant times in this matter. I have continued to remain active to the current time and have formed my opinions in close communications with many clinicians around the world based on in part our collective clinical experience with acute and convalescent COVID-19 cases as well as closely following the pre-print and published literature on the outbreak. I have specifically reviewed key published rare cases and reports concerning the possible recurrence of SARS-CoV-2 in patients who have survived an initial episode of COVID-19 illness.

OPINIONS

GENERAL COMMENTS

I have been requested to provide expert rebuttal to the opinions of Drs. Daniel Salmon, Brett Gilbert, and Jonathan Stallkamp. I have also reviewed Mrs. Gray's religious exemption request, deposition transcript, and Main Line Health's criteria for considering an exemption request. The report will begin with general information about what was known about the science

of COVID-19 at the time that Main Line Health instituted its policy and then address the comments made by the above individuals in their reports.

In June of 2021, the CDC reported the lowest number of cases since March of 2020 (the beginning of the COVID-19 pandemic). Sam Baker & Andrew Witherspoon, *COVID-19 Cases Hit Lowest Point in U.S. Since Pandemic Began*, AXIOS (June 3, 2021), https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582-4e69-aefb-3b5170268048.html Then by the start of October of 2021, the U.S. cases of, and hospitalizations from, COVID-19 continued their recent steady decline, as the country seemed to be moving past a July surge caused by the delta variant. https://www.marketwatch.com/story/u-s-covid-19-cases-and-hospitalizations-continue-to-decline-but-experts-lament-preventable-deaths-that-have-pushed-toll-above-700-000-11633358051?siteid=yhoof2 America's summer wave peaked at an average of nearly 176,000 cases per day, but plummeted 41 percent as of the first week in October. The number of COVID patients in hospitals, a lagging indicator, was down 25 percent since September 4th, and COVID deaths, which lagged even further, decreased as well. Further, overall, fewer and fewer COVID tests nationwide came back positive at this time: less than 6.5 percent currently (compared with more than 10 percent in late August). Based upon this data, "experts were predicting that the U.S. pandemic may finally be starting to peter out. While the virus may never fully disappear, it is expected to become endemic — just another less dangerous and disruptive threat that humans coexist with." https://news.yahoo.com/the-last-major-wave-of-infection-do-falling-covid-cases-signal-the-end-of-the-us-pandemic-203343478.html

Further, according to my research, herd immunity defined as freedom from second, third, etc instances of COVID-19 infection complicated by hospitalization and death is calculated by a specific formula, as

follows: ((CC*6) + V + (.15*P)) ÷ P = HIN.

CC= COVID-19 cases in the state

6= the current CDC multiplier[3]

V= number of vaccinated in the state

15% = the number of people in a given state that will not get COVID-19

P=Population of a state

HIN=Herd Immunity Totals

By this method of calculation, the United States had achieved herd immunity, meaning that the total of this calculation exceeds 100%. As vaccines continue to fail, we can expect cases of COVID-19, and the meaning of herd immunity applying to those fully protected by natural immunity and not that from vaccination. Despite expected incidents and prevalent cases, my opinion is that spread will be minimized and there will be no more large outbreak curves as the country experienced in November through early January, before the advent of widely deployed early treatment protocols. Because the randomized trials of all COVID-19 vaccines revealed less than 1% absolute risk reductions, and the then recent observation of widespread failure of COVID-19 vaccines in countries such as Israel, which had a substantial population vaccinated early in the pandemic, we can expect more vaccine failures in the United States and no fundamental impact of mass vaccination on the epidemic curves.

In my expert medical opinion, the epidemic spread of COVID-19, like all other respiratory viruses, notably influenza,[4] is driven by symptomatic persons; asymptomatic

[3] Centers for Disease Control and Prevention, Estimated Disease Burden of COVID-19 (May 19, 2021), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[4] Eleni Patrozou & Leonard A. Mermel, *Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?*, 124 Pub. Health Rep. 193 (2009).

spread is trivial and inconsequential (Cao et al, Madewell et al). A meta-analysis of contact tracing studies published in The Journal of the American Medical Association showed asymptomatic COVID-19 spread was negligible at 0.7%. Zachary J. Madewell, Ph.D.; Yang Yang, Ph.D.; Ira M. Longini Jr, Ph.D.; M. Elizabeth Halloran, MD, DSc; Natalie E. Dean, Ph.D., *Household Transmission* of SARS-CoV-2: A *Systematic Review* and *Meta-analysis*, JAMA Network Open, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited June 20, 2021).

Accordingly, a rational and ethical prevention measure to reduce the spread of COVID-19 is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID-19, should isolate themselves. Indeed, during the H1N1 influenza A pandemic, fully open, unmasked college campuses were advised by federal health officials, *"Flu-stricken college students should stay out of circulation"* and *"if they can't avoid contact they need to wear surgical masks."* Great Falls Tribune, *Advice: Flu-stricken college students should stay out of circulation, August 21, 2009,* page 5, section A, available at https://www.newspapers.com/image/243611045.

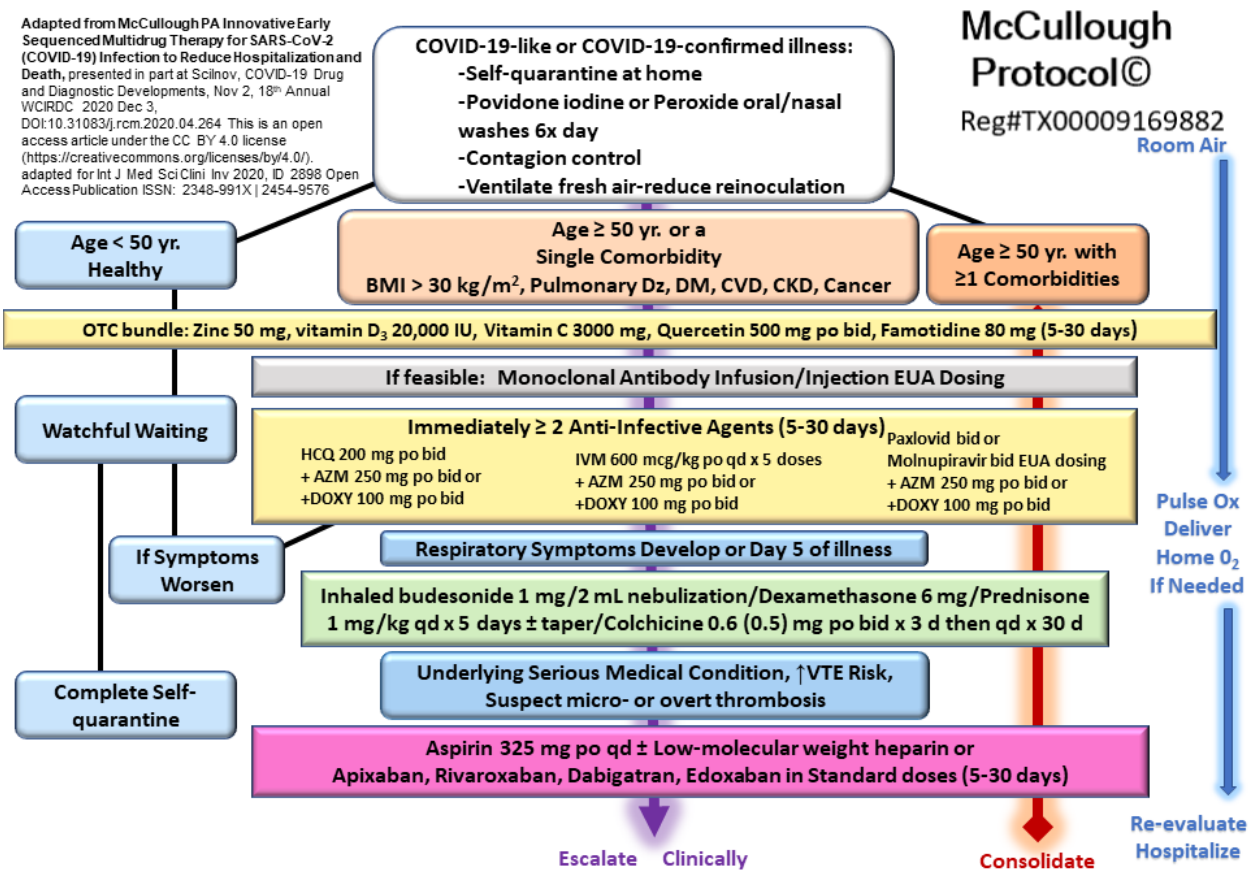
Even if individuals contract the virus, the treatment of the infection has improved tremendously since the advent of COVID-19. Studies have shown several different treatment strategies, which have proven effective. A combination of medications, supported by the Association of American Physicians and Surgeons, for a minimum of five days, and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability), has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, *Clinical*

Outcomes After Early Ambulatory Multidrug Therapy for High-risk SARS-CoV-2 (COVID-19) infection, Reviews in Cardiovascular Medicine (December 30, 2021), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 26, 2021), summarized in the Table below. **This approach has resulted in an ~85% reduction in hospitalization and death in high-risk individuals presenting with COVID-19.**[5]

~~**Table: COVID-19 Treatments**~~**Figure: McCullough Protocol**

~~Agent (drug)~~	~~Rationale~~
~~Zinc~~	~~Inhibits SARS-CoV-2 RNA synthesis~~
~~Hydroxychloroquine 200 mg po bid~~	~~Inhibits endosomal transfer of virions, anti-inflammatory~~
~~Ivermectin (200 mcg/kg) usual dose nuclear12 mg po qd x 3 days nucleus~~	~~Attenuates importin á/â-mediated transport of SARS-CoV-2 into~~
~~Azithromycin 250 mg po bid~~	~~Covers respiratory bacterial pathogens insecondary infection~~
~~Doxycycline 100 mg po bid~~	~~Covers respiratory bacterial pathogens in secondary infection~~
~~Inhaled budesonide, Dexamethasone 8 mg IM~~	~~Treats cytokine storm~~
~~Folate, thiamine, vitamin B-12~~	~~Reduce tissue oxidative stress~~
~~Intravenous fluid~~	~~Intravascular volume expansion~~

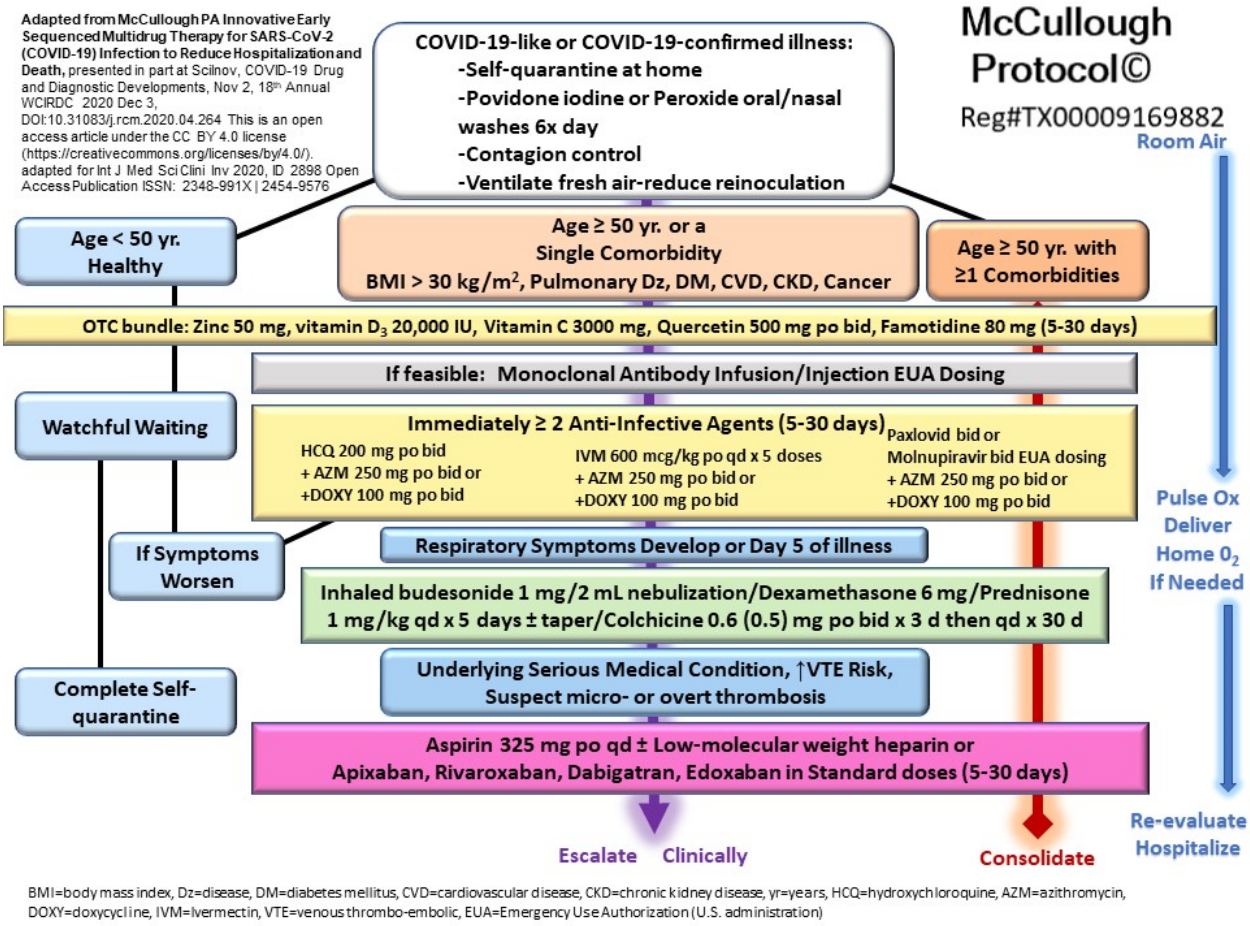
[5] https://ijirms.in/index.php/ijirms/article/view/1100



I, along with my colleagues, conducted the study referenced above, which evaluated patients between the ages of 12 and 89 years. The average age was 50.5 and 61.6% were women. The study found that primary care physicians can treat COVID-19 patients resulting in reduced rates of hospitalization and death. **The study showed that administration of the medicines and supplements shown in the Table produces a less than 2% chance of facing hospitalization or death among high-risk adults (age over 50 with medical problems). As this study was done with mainly higher-risk patients at the peak of the pandemic, this is a highly successful treatment plan and just one of the many new treatments that have been used in the last year including those admitted for COVID-19 that are covered in the NIH COVID-19 Guidelines**. *Id.; see also* National Institutes of Health, *Therapeutic Management of Adults With COVID-19*

(Updated May 24, 2021), https://www.COVID-19treatmentguidelines.nih.gov/management/therapeutic-management/ (last visited June 21, 2021).

The treatment of COVID-19 is summarized in the Figure below:



The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it was, unknown whether or not these products will change human genetic material, cause birth defects, reduce fertility, or cause cancer. Furthermore, The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines," or vaccines produced from gene therapy molecular platforms which, according to the United States Food and Drug Administration regulatory guidance,

are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. FDA. Food and Drug Administration. (*Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance* for *Industry*. FDA-2018-D-2173. 2020. Accessed July 13, 2021, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products). **The FDA has "advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product**, specifying that the long-term follow-up observation should include a minimum of **five years of annual examinations**, followed by ten years of annual queries of study subjects, either in person or by questionnaire." (*emphasis added*) **Thus, the administration of the Moderna, Pfizer, and JNJ vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up, which are currently not offered in the United States.** *(See,* EUA briefing documents for commitments as to follow up*:* Moderna[6], Pfizer[7], J&J[8])

These vaccines have a dangerous mechanism of action, in that they all cause the body to make an uncontrolled quantity of the foreign, pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks, probably for a longer period based on the late emergence of vaccine injury reports. This is unlike all other vaccines, where there is a set amount of antigen or live-attenuated virus. This means for Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. The Pfizer, Moderna, and JNJ vaccines, because they are different, are expected to

[6] https://www.fda.gov/media/144434/download
[7] https://www.fda.gov/media/144245/download
[8] https://www.fda.gov/media/146219/download

produce different libraries of limited antibodies to the now extinct wild-type spike protein. We know the spike protein produced by the vaccines is obsolete because the 17th UK Technical Report on SARS-CoV-2 Variants issued June 25, 2021, and the CDC June 19, 2021, Variant Report, both indicate the SARS-CoV-2 wild type virus to which all the vaccines were developed is now extinct.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf
https://COVID-19.cdc.gov/COVID-19-data tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fvariant-proportions.html#variant-proportions

The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells, in particular, causes the body's own immune system to react to these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years. *See, infra* ¶ *43 – 53.*

Because the neither the United States Food and Drug Administration nor the Centers for Disease Control have offered methods of risk mitigation for these serious adverse effects that can lead to permanent disability or death, no individual should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products. **Because the vaccine centers, CDC, FDA, and the vaccine manufacturers ask for the vaccine recipient to grant indemnification on the consent form before injection, all injuries incurred by individuals are at their own cost, which can be prohibitive depending on the needed procedures, hospitalizations, rehabilitation, and medications.**

In general, it is never good clinical practice to widely utilize novel biological products in populations that have not been tested in registrational trials. For COVID-19 vaccines, this includes COVID-19 survivors, those with prior suspected COVID-19 infection, those with positive SARS-CoV-2 serologies, pregnant women, and women of childbearing potential who cannot assure contraception. **Moreover, it is never good research practice to perform a large-scale clinical investigation without the necessary structure to ensure the safety and protection of human subjects**. These structures include a critical event committee, data safety monitoring board, and human ethics committee. These groups in large studies work to objectively assess the safety of the investigational product and research integrity. **The goal is mitigating risk and protecting human subjects. It is my understanding that the COVID-19 vaccine program as sponsored by the CDC and FDA lacked these safety structures.** It is my assessment that the COVID-19 clinical investigation has provided no meaningful risk mitigation for subjects (restricting groups, a special assessment of side effects, follow-up visits, or changes in the protocol to ensure or improve the safety of the program).[9]

The then current COVID-19 vaccines were not sufficiently protective against contracting COVID-19 to support its use beyond the previous voluntary participation in the CDC-sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died.

[9] https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers

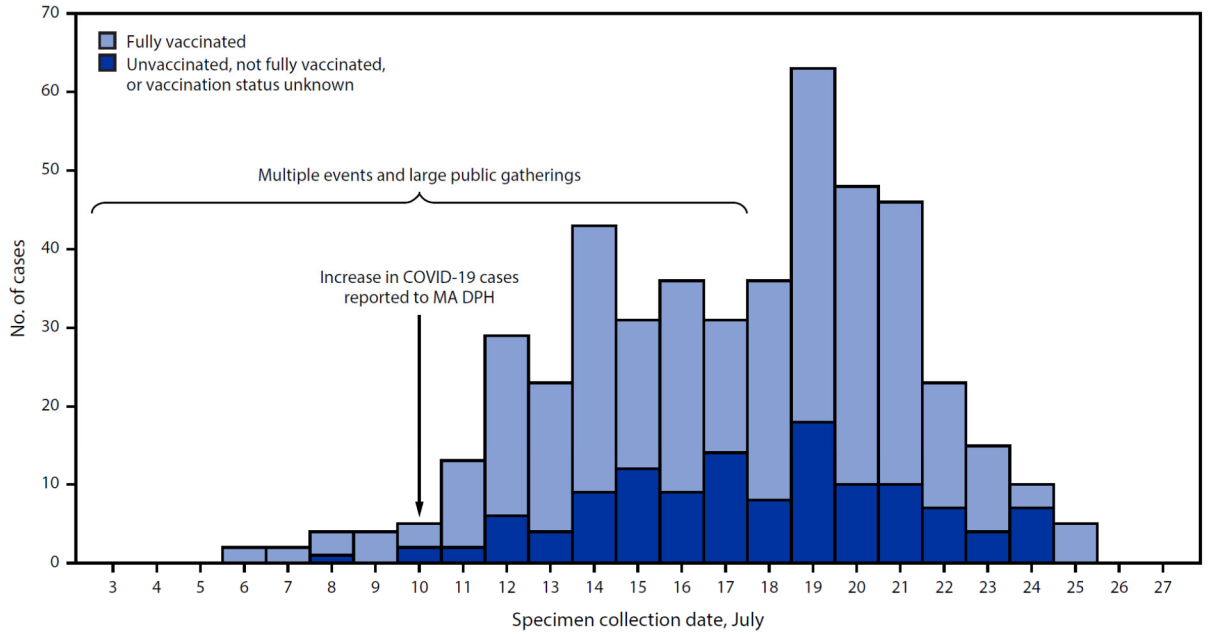
Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427 (28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). **None of these variants were encoded in the RNA or DNA of the then current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm). This overt asymmetric reporting will create a scientifically false narrative; namely, the false picture of only unvaccinated individuals developing COVID-19, when in reality patients who are fully vaccinated will be contracting breakthrough infections except for those vaccinated individuals who were previously immune from prior COVID-19 infection. Policies that relied upon this assumption are, in my opinion, fatally flawed and lead to discriminatory application when religious beliefs require spiritual discernment of secular experience.**

During the time in question in this case, he Delta variant of SARS-CoV-2 accounted for the majority of cases in the United Kingdom, Israel, and the United States. Because of progressive mutation of the spike protein, the virus ha achieved an immune escape from the COVID-19 vaccines with the most obvious example being Israel, where indiscriminate vaccination achieved 80% immunization rates. https://datadashboard.health.gov.il/COVID-19019/general. **This has promoted the emergence of the Delta variant as the dominant strain**

and because it is not adequately covered by the Pfizer COVID-19 vaccine, greater than 80% of COVID-19 cases have occurred in persons fully vaccinated, some now with failed boosters. This confirms the failure of the vaccines against COVID-19.

In the SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 17 25 June 2021, 92,056 cases had the Delta variant and 50/7235 fully vaccinated and 44/53,822 of the unvaccinated died. This indicates that the fully vaccinated who contract the Delta variant have an 8.6-fold increased risk for death, (95% CI 5.73-12.91), p < 0.0001, as compared to those who chose to remain unvaccinated, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf . **The CDC itself published a report titled: "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021" demonstrating complete failure of the COVID-19 in controlled spread of SARS-CoV-2 in congregate settings. My interpretation of this report is that the vaccines are not sufficiently effective to make the elective, investigation vaccine recommended for use beyond individual preference.** https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

FIGURE 1. SARS-CoV-2 infections (N = 469) associated with large public gatherings, by date of specimen collection and vaccination status* — Barnstable County, Massachusetts, July 2021



Abbreviation: MA DPH = Massachusetts Department of Public Health.
* Fully vaccinated was defined as ≥14 days after completion of state immunization registry–documented COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices.

The Wisconsin Department of Public Health had reported that vaccinated individuals were carrying the Delta variant in high viral loads and were equally infectious as the unvaccinated with Delta, implying that vaccination of one individual does not protect another against COVID-19. Among those tested, the vaccinated had similar viral loads to the unvaccinated, and thus, the vaccinated cannot be considered "more protected" than those who have declined vaccination. (https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v3)

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Kasen K. Riemersma, DVM, PhD[1]; Brittany E. Grogan, MPH[2]; Amanda Kita-Yarbro, MPH[2]; Peter Halfmann, PhD[1]; Anna Kocharian, MS[3]; Kelsey R. Florek, PhD[4]; Ryan Westergaard, MD, PhD[3,5]; Allen Bateman, PhD[4]; Gunnar E. Jeppson, BS[6]; Yoshihiro Kawaoka, DVM, PhD[1]; David H. O'Connor, PhD[7]; Thomas C. Friedrich, PhD[1]; Katarina M. Grande, MPH[2]

[1] Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; [2] Public Health Madison & Dane County, Madison, WI, USA; [3] Wisconsin Department of Health Services; [4] Wisconsin State Laboratory of Hygiene; [5] Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; [6] Exact Sciences, Madison, WI, USA; [7] Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

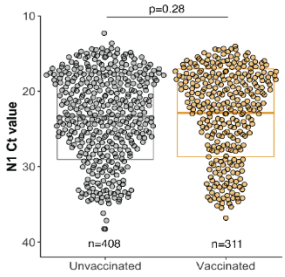


Figure 1. Distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing do not differ by vaccination status. N1 PCR Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between the groups by Welch two-sample t-test.

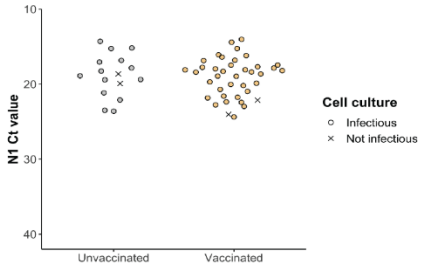


Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens without apparent CPE are represented by 'X'.

In 1990, the Vaccine Adverse Event Reporting System ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines. VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to the CDC and FDA. As a result, the VAERS database is subject to underreporting of meaningful clinical events. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID-19 Vaccines alone through October 1, 2021, is 778,683, up over 400,000 since June 18, 2021. Based on VAERS as of October 1, 2021, there were 16,310 COVID-19 vaccine deaths reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). See VAERS COVID-19 Vaccine Data. By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) for all vaccines

combined.[10] Thus, the COVID-19 mass vaccination is associated with at least a 101-fold increase in annualized vaccine deaths reported to VAERS. COVID-19 vaccine adverse events account for 99% of all vaccine-related Aes from December 2020 through the present in VAERS.

Increasingly the medical community acknowledged the possible risks and side effects of vaccination including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. See Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020 (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 26, 2021). Indeed, the Centers for Disease Control held emergency meetings on this issue and the medical community is responding to the crisis. It Is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. **Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis. (**McCullough PA, Philbin EF, Spertus JA, Kaatz S, Sandberg KR, Weaver

[10]Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the VaccineAdverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).

WD; Resource Utilization Among Congestive Heart Failure (REACH) Study. Confirmation of a heart failure epidemic: findings from the Resource Utilization Among Congestive Heart Failure (REACH) study. J Am Coll Cardiol. 2002 Jan 2;39(1):60-9. Doi: 10.1016/s0735-1097(01)01700-4. PMID: 11755288.)

Research at the time demonstrated that the COVID-19 vaccine was dangerous for those who have already had COVID-19 and have recovered with inferred robust, complete, and durable immunity. These patients were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials, the safety profile was therefore unknown when the products were approved for Emergency Use Authorization in 2020. There has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have well documented or even suspected prior COVID-19 illness. In fact, a medical study of United Kingdom healthcare workers who had already had COVID-19 and then received the vaccine found that they suffered higher rates of side effects than the average population. Rachel K. Raw, et al., Previous COVID-19 infection but not Long-COVID-19 is associated with increased adverse events following BNT162b2/Pfizer vaccination, medRxiv, https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021). The test group experienced more moderate to severe symptoms than the study group that did not previously have COVID-19. Id. The symptoms included fever, fatigue, myalgia-arthralgia, and lymphadenopathy. Id. Raw found that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline had a higher rate of vaccine reactions than those who were COVID-19 naïve. Id.

Mathioudakis et al. had reported that in 2020, in patients who underwent vaccination with either mRNA-based or vector-based COVID-19 vaccines, COVID-19-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.[11]

Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or joint pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)." (https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1).

Block had summarized 20 studies that confirm natural immunity is robust, complete and durable and cannot be improved upon by vaccination. Natural immunity is far superior to vaccine immunity, which has led to large numbers of vaccine failures, hospitalizations, and death. (Block J. Vaccinating people who have had covid-19: why doesn't natural immunity count in the US? BMJ. 2021 Sep 13;374:n2101. Doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.)

To my knowledge at the time, and currently, there are no studies that demonstrate the clinical benefit of COVID-19 vaccination in COVID-19 survivors or those with suspected COVID-19 illness or subclinical disease who have laboratory evidence of prior infection. **It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity, which by comparison has demonstrated massive failure including over 10,000 well-documented vaccine failure cases as reported by the CDC before tracking was stopped on May 31, 2021. There were no studies**

[11] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1

demonstrating the clinical benefit of COVID-19 vaccination in COVID-19 survivors and there were three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors, many of whom may be in the student population.

Multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent mildly or severely infected COVID-19 patients who are unvaccinated can have greater virus-neutralizing immunity—especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected. See Athina Kilpeläinen, et al., *Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1 (last visited June 26, 2021); Tongcui Ma, et al., Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 (last visited June 26, 2021); Claudia Gonzalez, et al., *Live virus 22eutralization testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2,* medRxiv (pre-print), https://www.medrxiv.org/ content/10.1101/2021.05.11.21256578vl (last visited June 21, 2021); Carmen Camara, et al. *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1 (last visited June 26, 2021); Ellie N. Ivanova, et al., *Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1 (last visited June 26, 2021);

Catherine J. Reynolds, et al, *Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose,* (pre-print), https://pubmed.ncbi.nlm.nih.gov/33931567/ (last visited June 21, 2021); Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670vl (last visited June 26, 2021).

Cleveland Clinic had studied their employees for the effects of natural immunity in unvaccinated people. Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, *Necessity of COVID-19 vaccination in previously infected individua*ls now summarized by Block (Block J. Vaccinating people who have had covid-19: why doesn't natural immunity count in the US? BMJ. 2021 Sep 13;374:n2101. Doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.) **They found zero SARS-CoV-2 reinfections during a 5-month follow-up among 1359 infected employees who were naturally immune and remained unvaccinated, and concluded such persons are "*unlikely to benefit from COVID-19 vaccination.*" Among those who were vaccinated, unlike the naturally immune, there were vaccine failure or breakthrough cases of COVID-19. Id.**

An analysis by Murchu et al demonstrated in 615,777 individuals that included well-documented COVID-19 as well as subclinical infections with positive serologies, that there was a negligible incidence (<1%) of COVID-19 over the long term. Murchu found no evidence of waning immunity over time, suggesting no possibility that future vaccination would be indicated for any reason. https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260. **A then recently published article in Nature reported that prior infection induces long-lived bone marrow plasma cells, which means the antibodies to prevent reinfection of COVID-19 are long-**

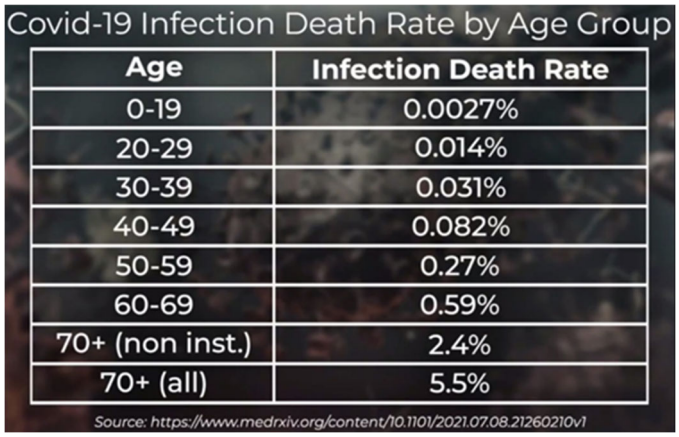
lasting. Jackson S. Turner et. al. *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, (May 24, 2021) https://www.nature.com/articles/s41586-021-03647-4 .

SPECIFIC COMMENTS

Dr. Salmon was asked to opine on specific questions regarding COVID-19, some that are relevant to Mrs. Gray's case and others that are not. For illustrative purposes only, I will organize this section to parallel Dr. Salmon's report. However, in so doing, I am not limiting my opinions in response to those headings and may also address them elsewhere in this report.

1. **Covid threat to patients and employees in September 2021**
   a. **In September 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations**?

While Covid could be a fatal disease for elderly and individuals with other comorbidities, in the summer of 2021, it was well documented and known that there was a very low mortality rate for persons less than 70 years old. https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v1.full.pdf+html



- At that time, it was also recognized that Covid was a treatable disease for most people. Early treatment regimens were widely available and utilized around the country from multiple sources, including the FLCCC, myself, and others. A combination of medications, supported by AAPS, has proven effective.

https://pubmed.ncbi.nlm.nih.gov/34130113/#:~:text=Data%20from%20nine%20studies%20found,%3E%2060%25%20reduction%20in%20mortality. NIH treatment guidelines later also included drugs such as Paxlovid or Molnupiravir. https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf.

b. **How did asymptomatic transmission impact the spread of COVID-19 in health care facilities**?

Dr. Salmon bases his discussion regarding asymptomatic transmission on an open modeling study from Jan 2021 JAMA Open Network. The paper is a summary of a modeling exercise, and not based on an actual randomized, controlled, clinical, empirical study. The study models various scenarios based on other studies that have questionable validity. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707

Rather than focus on this hypothetical modeling study, it is more appropriate to focus on the clinical data available at that time which showed that fully vaccinated individuals can and do transmit Covid. Asymptomatic transmission was not common. The epidemic spread of COVID-19, like all other respiratory viruses, including influenza, is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential. It is possible and probably likely that the vaccinated are more likely to spread the virus due to the tendency to think – "I'm vaccinated, I feel fine. So I'll go about my normal activities." This is exactly what happened in the previously discussed, well-publicized Provincetown, Massachusetts viral spread event in July 2021. At least 74% of Covid cases occurred in fully vaccinated persons, resulting from transmission from vaccinated individuals. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w

A series of published reports confirmed the trivial and inconsequential nature of asymptomatic spread. Madewell et al. *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*. Dec 2020, was a meta-analysis of contact tracing studies that showed asymptomatic COVID-19 spread, published in JAMA, was negligible at 0.7%. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102. ao et al. *Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China* wrote that "There was no evidence of transmission from asymptomatic positive persons to traced close contacts." https://www.nature.com/articles/s41467-020-19802-w. An article in April 2021 from the CDC Analysis of Asymptomatic and Presymptomatic Transmission in SARS-CoV-2 Outbreak, Germany, 2020 failed to demonstrate evidence of asymptomatic spread. https://wwwnc.cdc.gov/eid/article/27/4/20-4576_article. Finally, Mahmood et al. *Transmission frequency of COVID-19 through pre-symptomatic and asymptomatic patients* published "In the studied population, the risk of pre-symptomatic and asymptomatic transmission of COVID-19 was low, with transmission risks of 1.12% and 0.06% respectively. Pre-symptomatic infection becomes very rare in contacts made longer than 6 h before onset of symptoms." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8254450/. Glaringly, all of these articles were available and disregarded by Main Line Health and its experts when formulating its COVID-19 vaccination policy and considering exemption requests.

In the summer and fall of 2021, it was already evident that universal vaccination – even at 100% vaccinated levels – would not eliminate or possibly not even reduce the transmission of the virus. Numerous published reports from the summer and fall of 2021 showed that fully vaccinated have equal viral loads in the nasopharynx as determined by PCR testing as those who are unvaccinated. https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1

It was evident that the COVID-19 vaccines were progressively losing efficacy over the prevention of COVID-19 and, in widely vaccinated countries, up to 80% of COVID-19 cases were in the previously vaccinated, implying the vaccines were becoming obsolete with antigenic escape or resistance to variants (e.g. Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain. Thus, COVID-19 vaccination does not make a person less infectious, nor does it "protect" others.

In the summer and fall of 2021, it was increasingly known among "main-stream" experts that vaccine efficacy was waning rapidly and that natural immunity was protective against disease. On September 16, 2021, Francis Collins emailed to his colleagues at the NIH, including Anthony Fauci: "Interesting and pretty compelling evidence that VE [Vaccine Efficacy] is falling 5 – 6 months post vaccination for both infection and hospitalization for those over 65. Even for those 3 – 4 months out there is a trend towards worsening VE." Previously, in late August and early September 2021, Humetrix had been telling the CDC and FDA that: "…findings show a very significant decrease in VE … for Pfizer or Moderna." "73% of Covid-19 cases occurred in fully vaccinated individuals." Further, "Prior Covid-19 infection has a major protective effect against breakthrough hospitalization." https://icandecide.org/wp-content/uploads/2023/05/2022-07-29-Production_IR0669B_FDA-83-pages.pdf#page=3, https://globalcovidsummit.org/news/bettina-experton-md-and-humetrix-team-reveal-waning-vaccine-effectiveness, and https://www.scribd.com/document/530082359/Salus-Humetrix-VE-Study-2021-09-28a-1#.

Additional articles and a synopsis of them follows:

1. Brown et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings - Provincetown, Massachusetts, July 2021. "Among the 469 cases in Massachusetts residents, 346 (74%) occurred in persons who were

fully vaccinated" MMWR Morb Mortal Wkly Rep 2021; 70: 1059-1062. http://dx.doi.org/10.15585/mmwr.mm7031e2

2. Riemersma. Shedding of Infectious SARS-CoV-2 Despite Vaccination. Medrxiv July 2021. The vaccinated have similar viral loads to the unvaccinated, and thus, the vaccinated cannot be considered "more protected" than those who have declined vaccination. "We observed no significant effect of vaccine status alone on Ct value, nor when controlling for vaccine product or sex." "We detected infectious virus at similar rates, and at similar titers, in specimens from vaccinated and unvaccinated individuals. These data indicate that vaccinated individuals infected with Delta variants are capable of shedding infectious SARS-CoV-2 and could play a role in spreading COVID-19." "Vaccine effectiveness, particularly against symptomatic, test-positive SARS-CoV-2 infection, wanes with time after vaccine receipt." https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v7.full.pdf .
3. Acharya. No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant. Available online Sept 2021. "Over 20% of positive, vaccinated individuals had low Ct-values (<20), a third of which were asymptomatic when tested. This highlights the need for additional studies of the immunological status of such vaccine escapes and how infectious they are. If such individuals carry high loads of active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoing pandemic as the proportion of vaccinated individuals grows." https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1.full.pdf
4. Singanayagam et al. "Community transmission and Viral Load Kinetics of the SARS-Cov-2 Delta (B.1.617.2) Variant in Vaccinated and Unvaccinated Individuals in the UK: A Prospective, Longitudinal, Cohort Study," Published online Oct 2021. "Fully vaccinated

individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts." https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900648-4

5. Pouwels. Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. Published online October 2021. "Peak viral load, therefore, now appears similar in infected vaccinated and unvaccinated individuals, with potential implications for onward transmission risk." "This might be particularly important when vaccinated individuals are not aware of their infection status or perceive that their risk of transmission is low." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8674129/pdf/41591_2021_Article_1548.pdf

c. Was exposure to COVID-19 in health care setting an occupational hazard for employees?

The health care setting was no more hazardous than any other place of work. People were exposed every time they went into public spaces. In fact, there was less viral spread in the health care setting than many other places, including at home because of the use of universal precautions and masking efforts. Employees and patients were more likely to get Covid at home than at a MLH office where the staff could be testing daily and taking precautionary measures.

In the summer and fall of 2021, it was well documented that SARS-CoV-2 was most likely to spread in the home. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783544 https://www.cnn.com/2020/10/30/health/household-spread-covid-19-wellness/index.html and https://abcnews.go.com/Health/covid-19-spreads-easily-experts/story?id=74783036. Contact tracing demonstrated that Cleveland health care workers are contracting COVID-19 outside of work. "We have found the exact same thing since the beginning of the pandemic, and we continue

to see it now," said Dr. Robin Strosaker, University Hospitals' chief operating officer. "Almost all of our cases are acquired through community spread, and not in our hospitals." Nov 2020. https://www.cleveland.com/coronavirus/2020/11/contact-tracing-shows-cleveland-health-care-workers-are-contracting-covid-19-outside-of-work.html

e. Why were health care personnel high priority group (#1a) when vaccines had limited availability?

Dr. Salmon cites an article from the Guardian and Kaiser Health Network. This investigative report found that 3600 US Health Workers Died in Covid's first year. However, other clinical data showed that: "We found that the fatality rate in the US general population (2.48%) was more than 7-fold higher than that among HCWs (0.33%)." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9328912/.

2. Safety and Efficacy of COVID-19 Vaccines

Although Main Line Health entitled this section "Safety and Efficacy", the questions posed to the expert did not pose any question regarding vaccine safety and Dr. Salmon did not offer any specific comments on vaccine safety. However, in evaluating efficacy, one must perform a risk/benefit analysis in order to properly determine efficacy, permit individuals to make decisions consistent with their religious beliefs, and obtain proper patient consent.

a. What was the efficacy of vaccines available in September 2021?

First, it is important to recognize that the randomized trials of all COVID-19 vaccines available revealed less than a 1% absolute risk reduction. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9115787/pdf/IERV_0_2067531.pdf. Second, the Food and Drug Administration provided Emergency Use Authorization for the vaccines, not full vaccine approvals. Therefore, the vaccines had not undergone the rigors of regulatory testing.

No randomized, placebo-controlled trial of any COVID-19 vaccine has demonstrated statistically significant reductions in hospitalization or death. Interestingly, in the largest clinical trials program reported to date at the time, there were actually more deaths with the Pfizer/BioNTech COVID-19 vaccine than with the placebo. S.J. Thomas, et al., "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months," New Eng. J. Med (Nov. 4, 2021). https://www.nejm.org/doi/10.1056/NEJMoa2110345.

In the summer and fall of 2021, it was increasingly known that vaccine efficacy was waning rapidly and that natural immunity was protective against disease. On September 16, 2021, Francis Collins emailed to colleagues at the NIH including Anthony Fauci: "Interesting and pretty compelling evidence that VE [Vaccine Efficacy] is falling 5 – 6 months post vaccination for both infection and hospitalization for those over 65. Even for those 3 – 4 months out there is a trend towards worsening VE." Previously, in late August and early September, Humetrix had been telling the CDC and FDA that: "…findings show a very significant decrease in VE … for Pfizer or Moderna." "73% of Covid-19 cases occurred in fully vaccinated individuals." Further, "Prior Covid-19 infection has a major protective effect against breakthrough hospitalization." https://icandecide.org/wp-content/uploads/2023/05/2022-07-29-Production_IR0669B_FDA-83-pages.pdf#page=3 and https://globalcovidsummit.org/news/bettina-experton-md-and-humetrix-team-reveal-waning-vaccine-effectiveness and https://www.scribd.com/document/530082359/Salus-Humetrix-VE-Study-2021-09-28a-1#

b. In September 2021, were unvaccinated persons at an increased risk of contracting COVID and transmitting it to others who could not be vaccinated because of medical contraindications, were too young to be vaccinated or for whom the vaccine was not effective?

Numerous published reports from the summer and fall of 2021 showed that fully vaccinated individuals have equal viral loads in the nasopharynx as determined by PCR testing as those who are unvaccinated. Further, it was already evident that universal vaccination – even at 100% vaccinated levels – would not eliminate or possibly not even reduce the transmission of the virus. In November 2021, a FOIA request forced the CDC to admit they had no record of any unvaccinated person spreading the virus after recovering from Covid. Posted on 11/13/2021 https://www.swfinstitute.org/news/89518/foia-cdc-admits-no-record-of-unvaccinated-person-spreading-covid-after-recovering-from-covid .

Moreover, it was evident that the COVID-19 vaccines were progressively losing efficacy over the prevention of COVID-19 and, in widely vaccinated countries, up to 80% of COVID-19 cases were in the previously vaccinated, implying the vaccines were becoming obsolete with antigenic escape or resistance to variants (e.g. Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain. Thus, COVID-19 vaccination does not make a person less infectious, nor does it "protect" others. A summary of then available publications follows:

1. Brown et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings-Provincetown, Massachusetts, July 2021. "Among the 469 cases in Massachusetts residents, 346 (74%) occurred in persons who were fully vaccinated" MMWR Morb Mortal Wkly Rep 2021; 70: 1059-1062. http://dx.doi.org/10.15585/mmwr.mm7031e2
2. Riemersma. Shedding of Infectious SARS-CoV-2 Despite Vaccination. Available online Medrxiv July 2021. The vaccinated have similar viral loads

to the unvaccinated, and thus, the vaccinated cannot be considered "more protected" than those who have declined vaccination. "We observed no significant effect of vaccine status alone on Ct value, nor when controlling for vaccine product or sex." "We detected infectious virus at similar rates, and at similar titers, in specimens from vaccinated and unvaccinated individuals. This data indicated that vaccinated individuals infected with Delta variants could shed infectious SARS-CoV-2 and could play a role in spreading COVID-19." "Vaccine effectiveness, particularly against symptomatic, test-positive SARS-CoV-2 infection, wanes with time after vaccine receipt." https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v7.full.pdf

3. Acharya. No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant. Available online Sept 2021. "Over 20% of positive, vaccinated individuals had low Ct-values (<20), a third of which were asymptomatic when tested. This highlights the need for additional studies of the immunological status of such vaccine escapes and how infectious they are. If such individuals carry high loads of active virus, asymptomatic vaccinated individuals may increasingly contribute to the ongoing pandemic as the proportion of vaccinated individuals grows." https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1.full.pdf
4. Singanayagam et al. "Community transmission and Viral Load Kinetics of the SARS-Cov-2 Delta (B.1.617.2) Variant in Vaccinated and Unvaccinated Individuals in the UK: A Prospective, Longitudinal, Cohort Study," Published

online Oct 2021. "Fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts." https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900648-4

5. Pouwels. Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. Published online October 2021. "Peak viral load, therefore, now appears similar in infected vaccinated and unvaccinated individuals, with potential implications for onward transmission risk." "This might be particularly important when vaccinated individuals are not aware of their infection status or perceive that their risk of transmission is low." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8674129/pdf/41591_2021_Article_1548.pdf

6. The MLH expert states that "the vaccines reduce transmission to others." However, the vaccine manufacturers did not study whether the vaccines reduce transmission so this claim is incorrect.

c. In September 2021, did the science indicate that "natural immunity" was as effective as vaccination?

By the summer and fall of 2021, it was evident that vaccine efficacy was declining significantly on a monthly basis, and it was also evident that natural immunity acquired by contracting and recovering from COVID-19 is robust and durable and provides excellent protection against subsequent infection with SARS-CoV-2 and serious outcomes such as

hospitalization or death. It was well documented by the summer and fall of 2021 that natural immunity was at least as good as vaccinations.

Dr. Salmon does not accurately portray the level of knowledge that was available regarding natural immunity. In fact, he ignores the available knowledge that showed natural immunity was effective and durable. He also opined that it was unknown regarding the duration of efficacy from natural immunity, but failed to acknowledge that recovering from prior infection generates a lasting immune response, a basic scientific fact in immunology and infectious disease.

Interestingly, it was the duration of efficacy of the vaccines that should have been questioned. Emerging data at the time regarding duration of efficacy from vaccines showed rapid decline and durability of immunity from primary infection, even against the then emerging Delta variant. Namely, a timeline of then available studies revealed (hyperlinks provided):

1. June 2021 Necessity of COVID-19 vaccination in previously infected individuals This study followed 52,238 employees of the Cleveland Clinic Health System in Ohio. “Conclusions: Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.” For previously infected people, the cumulative incidence of re-infection “remained almost zero.” According to the study, "Not one of the 1,359 previously infected subjects who remained unvaccinated had a [Covid-19] infection over the duration of the study” and vaccination did not reduce the risk.
2. July 2021. Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory

B and T cells This study followed 254 Covid-19 patients for up to 8 months and concluded they had "durable broad-based immune responses." In fact, even very mild Covid-19 infection also protected the patients from an earlier version of "SARS" coronavirus that first emerged around 2003, and against Covid-19 variants. "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients," concludes the study scientists.

3. August 2021. MMWR. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. "Analysis of nursing home COVID-19 data from NHSN indicated a significant decline in effectiveness of full mRNA COVID-19 vaccination against laboratory-confirmed SARS-CoV-2 infection, from 74.7% during the pre-Delta period (March 1–May 9, 2021) to 53.1% during the period when the Delta variant predominated in the United States." https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7034-h.pdf

4. It was increasingly known that vaccine efficacy was waning rapidly and that natural immunity was protective against disease. As mentioned previously, Francis Collins emailed colleagues at the NIH including Anthony Fauci on September 16, 2021: "Interesting and pretty compelling evidence that VE [Vaccine Efficacy] is falling 5 – 6 months post vaccination for both infection and hospitalization for those over 65. Even for those 3 – 4 months out there

is a trend towards worsening VE." Previously, in late August and early September, Humetrix had been telling the CDC and FDA that: "…findings show a very significant decrease in VE … for Pfizer or Moderna." "73% of Covid-19 cases occurred in fully vaccinated individuals." Further, "Prior Covid-19 infection has a major protective effect against breakthrough hospitalization." https://icandecide.org/wp-content/uploads/2023/05/2022-07-29-Production_IR0669B_FDA-83-pages.pdf#page=3 and https://globalcovidsummit.org/news/bettina-experton-md-and-humetrix-team-reveal-waning-vaccine-effectiveness and https://www.scribd.com/document/530082359/Salus-Humetrix-VE-Study-2021-09-28a-1#

5. September 2021. Vaccinating people who have had Covid-19: why doesn't natural immunity count in the US? "If natural immunity is strongly protective, as the evidence to date suggests it is, then vaccinating people who have had Covid-19 would seem to offer nothing or very little to benefit, logically leaving only harms—both the harms we already know about as well as those still unknown," says Christine Stabell Benn, vaccinologist and professor in global health at the University of Southern Denmark. https://www.bmj.com/content/bmj/374/bmj.n2101.full.pdf
6. October 2021. Centers for Disease Control. Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity. "Available evidence shows that fully vaccinated individuals and those previously infected with SARS-CoV-2 each have a low risk of subsequent infection for at least 6

months." https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html

7. June 2021. Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar This study of airline passengers in Qatar found that the incidence of reinfection is similarly low in both groups.
8. May 2021. SARS-CoV-2 specific memory B-cells from individuals with diverse disease severities recognize SARS-CoV-2 variants of concern This study found strong immune signals in people who had previously been infected with Covid-19, including "those [who] experienced asymptomatic or mild disease." The study concludes there is "reason for optimism" regarding the capacity of prior infection "to limit disease severity and transmission of variants of concern as they continue to arise and circulate."
9. May 2021. A population-based analysis of the longevity of SARS-CoV-2 antibody seropositivity in the United States This study of real-world data extended the timeframe of available data indicating that patients have strong immune indicators for "almost a year post-natural infection of COVID-19." The study concludes the immune response after natural infection "may persist for longer than previously thought, thereby providing evidence of sustainability that may influence post-pandemic planning."
10. May 2021. SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans, This study published in Nature examined bone marrow of previously infected patients and found that even mild infection with Covid-

19 “induces robust antigen-specific, long-lived humoral immune memory in humans.” The study indicates "People who have had mild illness develop antibody-producing cells that can last lifetime.”

11. May 2021. World Health Organization (WHO) scientific brief This scientific brief issued by WHO states that after natural infection with Covid-19, “available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months.”
12. May 2020. Detection of SARS-CoV-2-Specific Humoral and Cellular Immunity in COVID-19 Convalescent Individuals, This study found humoral and cellular immunity in recovered Covid patients. "Production of S-RBD-specific antibodies were readily detected in recovered patients. Moreover, we observed virus-neutralization activities in these recovered patients," wrote the study authors. The adaptive immune system consists of three major lymphocyte types: B cells (antibody producing cells), $CD4^+$ T cells (helper T cells), and $CD8^+$ T cells (cytotoxic, or killer, T cells
13. April 2021. Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel, This study from Israel found a slight advantage to natural infection over vaccination when it comes to preventing a reinfection and severe illness from Covid-19. The study authors concluded, "Our results question the need to vaccinate previously-infected individuals." https://www.wjla.com/news/nation-world/natural-covid-infection-provides-similar-protection-to-vaccines-israeli-study-shows

14. March 2021. A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report, This study found a rare Covid-19 positive test "reinfection" rate of 1 per 1,000 recoveries.
15. Jan 2021. Lasting immunity found after recovery from COVID-19, Research funded by the National Institutes of Health and published in *Science* early in the Covid-19 vaccine effort found the "immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection"
16. Jan 2021. SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks, This study found Covid-19 natural infection "appears to elicit strong protection against reinfection" for at least seven months. "Reinfection is "rare," concludes the scientists.
17. March 2021. Negligible impact of SARS-CoV-2 variants on $CD4^+$ and $CD8^+$ T cell reactivity in COVID-19 exposed donors and vaccinees, This study concluded "T cell" immune response in former Covid-19 patients likely continues to protect amid Covid-19 variants.
18. Nov 2020. Orthogonal SARS-CoV-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humoral Immunity, This study found that "neutralizing antibodies are stably produced for at least 5–7 months" after a patient is infected with Covid-19.
19. July 2020. SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls. This study found that all patients who recently recovered from Covid-19 produced immunity-strong T cells that

recognize multiple parts of Covid-19. They also evaluated blood samples from 23 people who had survived a 2003 outbreak of a coronavirus: SARS (Cov-1). These people still had lasting memory T cells 17 years after the outbreak. Those memory T cells, acquired in response to SARS-CoV-1, also recognized parts of SARS-CoV-2. Much of the study on the immune response to SARS-CoV-2, the novel coronavirus that causes COVID-19, has focused on the production of antibodies. But memory T cells play an important role in the ability of our immune systems to protect us against many viral infections, including COVID-19.

20. March 2021 T cells recognize recent SARS-CoV-2 variants. https://www.nih.gov/news-events/news-releases/t-cells-recognize-recent-sars-cov-2-variants

21. Feb 2021 Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection https://science.sciencemag.org/content/371/6529/eabf4063

22. 2021 May. Op-Ed: Quit Ignoring Natural COVID Immunity - Antibody testing and proof of prior infection can allow more people to return to normal https://www.medpagetoday.com/infectiousdisease/covid19/92836

23. 2021 May. WHO Scientific Brief COVID-19 natural immunity. Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months). https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-

2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y

24. March 2021. Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection. https://www.nature.com/articles/s41467-021-22036-z

25. June 2020. Potent antibodies found in people recovered from COVID-19. https://www.nih.gov/news-events/nih-research-matters/potent-antibodies-found-people-recovered-covid-19

26. Feb 2021. SARS-CoV-2 re-infection risk in Austria. Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies. https://pubmed.ncbi.nlm.nih.gov/33583018/

27. April 2021. SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multi-center, prospective cohort study. https://pubmed.ncbi.nlm.nih.gov/33844963/

28. June 2021. Incidence of SARS-CoV-2 infection according to baseline antibody status in staff and residents of 100 long-term care facilities (VIVALDI): a prospective cohort study. "The presence of IgG antibodies to nucleocapsid protein was associated with substantially reduced risk of reinfection in staff and residents for up to 10 months after primary infection." https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568(21)00093-3/fulltext

29. Aug 2021. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. Having SARS-CoV-

2 once confers much greater immunity than a vaccine. https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital Study from Israel shows that SARS-CoV-2-naïve vaccinees had a **13-fold increased risk for breakthrough infection with the Delta variant** (emphasis added) compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for symptomatic disease as well. https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

30. Sept 2021. Natural Immunity to covid is powerful. Policy makers appear afraid to say so. Article in the Washington Post. https://www.washingtonpost.com/outlook/2021/09/15/natural-immunity-vaccine-mandate/

31. April 2021. Unbiased interrogation of memory B cells from convalescent COVID-19 patients reveals a broad antiviral humoral response targeting SARS-CoV-2 antigens beyond the spike protein. "Patients who recover from SARS-CoV-2 infections produce antibodies and antigen-specific T cells against multiple viral proteins." https://pubmed.ncbi.nlm.nih.gov/33937741/

32. July 2021. Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v2.full.pdf+html

33. October 2021. Duration of Severe Acute Respiratory Syndrome Coronavirus 2 Natural Immunity and Protection Against the Delta Variant: A Retrospective Cohort Study. "SARS-CoV-2 infection is highly protective against reinfection with the Delta variant. Immunity from prior infection lasts for at least 13 months." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8690283/pdf/ciab999.pdf

34. Nov 2021. Lancet. Klausner et al. Protective immunity after recovery from SARS-CoV-2 infection. "Clinicians should remain optimistic regarding the protective effect of recovery from previous infection. Community immunity to control the SARS-CoV-2 epidemic can be reached with the acquired immunity due to either previous infection or vaccination." https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900676-9

35. Oct 2021. COVID Immunity through infection or vaccination: Are they equal? "Evidence is growing that contracting SARS-CoV-2, the virus that causes COVID-19, is generally as effective as vaccination at stimulating your immune system to prevent the disease." https://health.wusf.usf.edu/health-news-florida/2021-10-08/covid-immunity-through-infection-or-vaccination-are-they-equal

36. Dec 2021. Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar. Study showed that prior infection was 97.3% protective against a second severe infection. https://www.nejm.org/doi/full/10.1056/nejmoa2114114.

3. Justification for mandatory Covid vaccine policy by health care institutions

b. In September 2021, were mandatory COVID-19 vaccine policies a critical protective action for health care institutions to protect patients and staff?

The COVID-19 vaccine is dangerous for those who have already had COVID-19 and have recovered with inferred robust and durable immunity. Individuals who recovered from Covid were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials, the safety profile was unknown when the products were approved for Emergency Use Authorization in 2020.

There has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have had well documented or even suspected prior COVID-19 illness. There are no randomized placebo-controlled randomized trials of COVID-19 vaccination given to persons who have already had the infection that demonstrate clinical benefit in reducing any serious outcome of the illness including hospitalization and death. In fact, the Food and Drug Administration and the vaccine manufacturers specifically excluded COVID-19 recovered persons from the randomized trials of vaccination because that group had no opportunity to benefit or had unacceptable safety risks.

Numerous studies have demonstrated that when COVID-19 recovered patients take a COVID-19 vaccination, they can suffer high side-effects including hospitalization. For example,

1. March 2021. Mathioudakis et al. Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey. "A prior COVID-19 infection was associated with an 8% increase in the risk of having any side effects after the first vaccine dose. We also observed a significantly increased risk of self-reported fever, breathlessness, flu-like illness, fatigue, local reactions and "other" side effects. Among those experiencing side effects,

a prior COVID-19 infection was associated with an increased severity of any side effect, local side effects or fatigue ($p < 0.001$). More importantly, a prior COVID-19 infection was associated with the risk of experiencing a severe side effect requiring hospital care. … A similar increase in the risk of any side effects following the second dose in those with a prior COVID-19 infection was also noted." https://pdfs.semanticscholar.org/27e1/9a78e49b07198baf8b9b41e84b8ee1b38be7.pdf

2. May 2021. Raw et al. Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination. "We read with interest the study recently published by Tré-Hardy et al., who reported that Adverse Events (AEs) after the first dose of mRNA-1273/Moderna vaccine were greater in those previously infected with COVID-191. Their findings are consistent with other studies that suggest mRNA vaccines may cause more AEs in those with a history SARS-CoV-2 infection." "This study of healthcare workers demonstrated that prior COVID-19, but not Long-COVID, was associated with increased risk of AEs following BNT162b2/Pfizer vaccination, although there was no relationship with duration since COVID-19 illness. Women and younger individuals were also more likely to report AEs. Our study adds to other reports supporting the wider understanding of AEs following COVID-19 vaccination. … Our study also adds weight to the question of whether a second dose of mRNA vaccine is necessary in those with previous COVID-19, assuming effective immunity is established after the first dose. This is relevant, given that Tre-Hardy's and other studies have reported worse AEs following second doses of vaccine." https://www.journalofinfection.com/article/S0163-4453(21)00277-2/fulltext

3. Based on VAERS as of October 1, 2021, there were 16,310 COVID-19 vaccine deaths reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). Thus, the COVID-19 mass

vaccination was already associated with at least a 101-fold increase in annualized vaccine deaths reported to VAERS.

There were alternatives to a vaccine mandate. Although the tests available for COVID-19 are not perfect, they are accurate as diagnostic aids in patients who are acutely ill with suspected COVID-19. A regime of testing symptomatic personnel and isolating those who test positive would do far more than vaccine mandates to slow the transmission of COVID-19. Furthermore, given the well documented value of natural immunity, Main Line Health also could have provided vaccine exemptions to all employees with proof of prior Covid infection.

Although MLH experts seem to argue that all staff had to be vaccinated to achieve its goals, universal vaccination was never warranted nor supported by scientific data. Conventional wisdom at the time suggested that 70 to 90% of people would need to have immunity (via vaccine or via prior infection). Therefore, it would be unnecessary to vaccinate EVERY employee. Instead, MLH could target 70 to 90% immunity. Indeed, the Centers for Disease Control's own data suggested that the incidence of disease was not further decreased in a high risk population who exhibited greater than 75% vaccination rates. There has been a question whether herd Immunity can be achieved through vaccination when dealing with a mutating virus like SARS-CoV-2. https://hive.rochesterregional.org/2023/02/herd-immunity-covid. For example, see the following studies:

1. The Relationship Between Vaccines and Herd Immunity. "In the case of COVID-19, health professionals estimate 70-90% of the population must be immune in order to achieve herd immunity." April 2021. https://www.publichealth.columbia.edu/news/relationship-between-vaccines-herd-immunity

2. When Could the United States Reach Herd Immunity? It's Complicated. NY Times, Feb 2021. By Matthew Conlen and Charlie Smart. "One answer lies in herd immunity, the point when enough people are immune to the virus that it can no longer spread through the population. Getting there, however, depends not just on how quickly we can vaccinate but on other factors, too, like how many people have already been infected and how easily the virus spreads. The exact threshold for herd immunity for the coronavirus is unknown, but recent estimates range from 70 percent to 90 percent. Much is still unknown about how long immunity from vaccines will last, or how well the vaccines will protect against new variants of the virus. The estimates also assume that the vaccine prevents infection rather than just reducing the severity of coronavirus symptoms. The spread of new virus variants makes it impossible to put a firm date on when we'll reach herd immunity or when the pandemic will end. There's a chance a mutation could lead to a version of the virus that doesn't respond to existing immunity, leading us to start the journey to herd immunity all over again. Dr. Lee said that coronaviruses have relatively high mutation rates and that it is likely that new variants of the virus will continue to emerge. "The question will be how different might these variants be," he said." https://www.nytimes.com/interactive/2021/02/20/us/us-herd-immunity-covid.html?action=click&module=RelatedLinks&pgtype=Article

3. Interestingly, Dr. Salmon promotes flu vaccine mandates, even though it has been widely known for years that the flu vaccines have very low efficacy and are of debatable clinical value except those who are at high risk of disease from the flu virus. He continues to hold this view, and other biases favoring mass vaccinations, even though multi-year data shows that a vaccine does not work particularly well. As shown in, https://www.cdc.gov/flu/vaccines-work/past-seasons-estimates.html

Winter	Overall Vaccine Efficacy (%)
2011-12	47%
2012-13	49%
2013-14	52%
2014-15	19%
2015-16	48%
2016-17	40%
2017-18	38%
2018-19	29%
2019-20	39%
2020-21**	n/a
2021-22	36%

- 2020-2021 flu vaccine effectiveness was not estimated due to low flu virus circulation

Furthermore, inactivated influenza vaccines "probably reduce influenza in healthy adults from 2.3% without vaccination to 0.9%." This means that out of every 100 healthy adults vaccinated, 99 get no benefit against laboratory confirmed influenza. Cochran review 01 February, 2018. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001269.pub6/full?highlightAbstract=influenza%7Cinfluenz%7Cvaccin%7Cvaccine. In other words, 71 healthy adults need to be vaccinated to prevent one of them experiencing influenza. Vaccination may lead to a small reduction in the risk of hospitalization in healthy adults, from 14.7% to 14.1%, but the confidence interval is wide. These vaccines may lead to little or no small reduction in days off work but work force issues are touted by the Defendants in their rationale for mandatory vaccination policies.

4. Impact of medical and religious exemption requests on health care institutions

a. What were the clinical contraindications to receiving the COVID vaccine?

b. How did non-medical vaccine exemption requests impact the efficacy of vaccine requirements and patient safety?

1. Dr. Salmon states that: "Unvaccinated persons (those with non-medical exemptions) are at increased risk of contracting disease and transmitting disease to others who cannot be vaccinated (because of medical contraindications), are too young to be vaccinated, or who are vaccinated but the vaccine did not work for them (no vaccine is 100% effective)." There

simply is no clinical data to support this statement and Dr. Salmon fails to provide any evidence himself.

c. Did exemptions seriously undermine the efficacy of a vaccination requirement?

d. Did health care institutions have a responsibility to patients and staff to establish and implement a process for evaluating exemption requests rather than simply rubber-stamping requests?

    1. Dr. Salmon states that: "As previously described, individuals who are granted exemptions to immunization requirements are at increased risk of contracting and transmitting vaccine preventable diseases. The greater the number of religious exemptions the higher the risk of COVID-19 infections and transmission." This statement is not supported by clinical data.

e. How did exemptions impact the operations of the health care institutions?

f. How effective were alternative infection control strategies (masking, testing, social distancing) in health care institutions?

In contrast to the statements made by Dr. Salmon, evidence exists to the contrary. Mandatory employee Covid vaccination policies have been of questionable value and worthy of debate. In November 2021, a FOIA request led the CDC to admit they had no record of any unvaccinated person spreading the virus after recovering from Covid. Posted on 11/13/2021 https://www.swfinstitute.org/news/89518/foia-cdc-admits-no-record-of-unvaccinated-person-spreading-covid-after-recovering-from-covid. The Covid vaccines were not studied to demonstrate that they contained the virus or prevented transmission. The vaccines were tested to determine whether they prevented severe illness. Therefore, there was no data to support the

"public health value" of mass vaccination (especially in people with little to no risk of suffering severe Covid illness) and the subsequent detrimental sequalae.

While the vaccines temporarily protected high-risk groups like the elderly and/or those who had significant health comorbidities, these effects were waning as well. The vaccines did not stop the spread of SARS-CoV-2. In fact, vaccinated people were walking around unwittingly spreading the virus. As discussed previously, in the summer and fall of 2021, it was well documented that asymptomatic Covid patients were spreading SARS-CoV-2. The goal of mass vaccination campaigns was to get to herd immunity as discussed above. In the summer and fall of 2021, health "experts" were arguing that Covid "herd immunity" would occur once 70 to 90% of people in a setting had immunity (either from natural infection and/or vaccination). https://www.webmd.com/covid/what-is-herd-immunity#:~:text=There%20was%20a%20big%20push,immunity%20has%20not%20been%20achieved.

MLH has disclosed they received denied approximately 100 requests for religious exemption. According to their website data, MLH has over 10,000 employees and 2,000 physicians. Therefore, had MLH granted religious exemptions to these additional 100 applicants, that would constitute only an incremental 0.8% of all MLH staff. There are no logical scientific grounds to argue that providing religious exemptions to less than 1% of the staff would lead to a "pandemic surge". In fact, allowing all 100 religious exemption requests would still enable MLH to have almost 100% staff vaccination levels.

Masking, social distancing, and testing are indeed all imperfect methods to attempt to contain SARS-CoV-2. These methods are imperfect related to all people, whether vaccinated or not.

Clinical evidence about the vaccines does not exist to prove that vaccinating perfectly healthy people will lead to "protecting patients" or the vulnerable. While there was possibly a small subset of patients who found temporary health benefit from the Covid vaccines (elderly, people with significant comorbidities, people without prior SARS-CoV-2 infection), the vaccines were not beneficial as a mass vaccine campaign because they were not proven to lower viral spread. As mentioned previously, it is likely that the vaccinated are more likely to spread the virus due to the tendency to think – "I'm vaccinated, I feel fine. So I'll go about my normal activities." This is exactly what happened in the well-publicized Provincetown, Massachusetts viral spread event in July 2021. 74% of Covid cases occurred in fully vaccinated persons. Vaccinated people were out and about and spreading the virus. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w

5. Anti-vaccine movement's impact on mandatory vaccine policies

a. Was there an anti-vax movement that impacted COVID-19 vaccine hesitancy in September 2021?

While the consideration of political ideologies is important, a religious exemption request should transcend politics. Regardless of their religious beliefs, Americans have the right to appropriately question the value of any medical therapy. This includes the value, safety, and efficacy of the Covid vaccines which had bypassed the normal development process, safety evaluation, and regulatory scrutiny and based upon their belief in an ultimate Deity, may have a spiritual imperative to do so. Having a sincerely held religious belief does not exclude the ability of an individual to have secular opinions.

It is important to recognize that the clinical trials that supported the Emergency Use Authorizations were only a few months in duration. As described by Johns Hopkins, "A typical

vaccine development timeline takes 5 to 10 years, and sometimes longer, to assess whether the vaccine is safe and efficacious in clinical trials, complete the regulatory approval processes, and manufacture sufficient quantity of vaccine doses for widespread distribution." Therefore, the vaccines were grossly under-studied as compared to every other vaccine ever approved by the FDA.

https://coronavirus.jhu.edu/vaccines/timeline#:~:text=A%20typical%20vaccine%20development%20timeline,vaccine%20doses%20for%20widespread%20distribution.

The CDC itself commented on the development process: "Research and Discovery: In this early stage of vaccine development, researchers explore their idea for a potential vaccine. Vaccine development often takes 10-15 years of laboratory research." https://www.cdc.gov/vaccines/basics/test-approve.html.

"How long, on average, does full FDA approval take compared with EUA? According to one study, over the past decade, the FDA approved 21 vaccines, mostly for flu or meningococcus. The median clinical development period (meaning from a Phase I trial to approval) was just over 8 years, including a median FDA review period of about a year. For comparison, the COVID-19 vaccine from Pfizer-BioNTech, which was the first to receive an EUA, was under clinical development for six months before it submitted its EUA. An EUA was granted in less than a month; full approval was issued eight months later." https://www.yalemedicine.org/news/what-does-eua-mean. In September 2021, Americans remained deeply divided about Covid vaccine requirements. In fact, "The public is split about evenly, 51% to 49%, on whether requiring proof of vaccination for everyday activities is an acceptable way to increase the vaccination rate, or an unacceptable infringement on personal rights." https://www.cnn.com/2021/09/13/politics/cnn-poll-coronavirus-vaccine-mandates/index.html.

Because of the lack of scientific clarity, individuals were hesitant to take the Covid-19 vaccine or declined due to safety concerns. In such a circumstance, it is appropriate for each individual to question the risk / benefit of vaccines. Religious beliefs may mandate this discernment through the lens of religion. Regardless of one's beliefs, however, it is mandatory from the medical perspective that patients receive informed consent to determine if medical therapy is appropriate for them.

"Informed consent is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. … Informed consent is both an ethical and legal obligation of medical practitioners in the US and originates from the patient's right to direct what happens to their body. … The Joint Commission requires documentation of all the elements of informed consent "in a form, progress notes or elsewhere in the record." The following are the required elements for documentation of the informed consent discussion: (1) the nature of the procedure, (2) the risks and benefits and the procedure, (3) reasonable alternatives, (4) risks and benefits of alternatives, and (5) assessment of the patient's understanding of elements 1 through 4. … It is the obligation of the provider to make it clear that the patient is participating in the decision-making process and avoid making the patient feel forced to agree to with the provider. The provider must make a recommendation and provide their reasoning for said recommendation." https://www.ncbi.nlm.nih.gov/books/NBK430827/?report=printable

Data available in summer and fall of 2021 already suggested that the COVID-19 vaccines had adverse events, led to disability and even death. COVID-19 vaccinations were generating record numbers of fatal and nonfatal organ injury syndromes according to over 1,000 publications in the preprint and PUBMED citation systems. There are over 200 published papers on COVID-19 vaccine-induced myocarditis reported with all the genetic vaccines. The FDA has warnings on the

investigation products from Pfizer/BioNTech and Moderna for the risks of myocarditis (heart damage). Myocarditis had also been reported in the literature with the Janssen and AstraZeneca vaccines. Fatal cases of myocarditis have been reported by Gill, Choi, and Verma. Fatal cases of vaccine-induced thrombocytopenic purpura, hepatitis C reactivation, venous thromboembolism, and anaphylaxis had been published indicating the COVID-19 as the proximate cause of death. The US CDC VAERS system, which is known to represent an under-reporting of verified events, has disclosed that COVID-19 vaccination has led to more than 12,000 deaths and more than 13,000 permanently disabled Americans. "VAERS COVID Vaccine Adverse Event Reports," Open VAERS https://openvaers.com/covid-data/.

These findings further highlight that the FDA and manufacturers hurried these vaccines to market without appropriate long-term testing. Individuals, regardless of whether their religious beliefs motivated discernment or whether they considered it in a purely secular fashion, were certainly justified in being hesitant to take the shots, given these significant safety concerns.

The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) were rushed through the development and regulatory process. They did not undergo typical preclinical animal studies for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. It is unknown whether these products can change human genetic material, cause birth defects, reduce fertility, or cause cancer. The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID-19 Vaccines alone through October 1, 2021 was 778,683 and rising rapidly with an increase greater than 400,000 since June 18, 2021. Based on VAERS as of October 1, 2021, there were 16,310 COVID-19 vaccine deaths reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). See VAERS COVID-19 Vaccine Data. Thus, the COVID-19 mass vaccination was associated with at least a 100-fold increase in annualized vaccine deaths reported to VAERS.

Since Main Line Heath has offered Dr. Salmon's opinions to justify its application of its COVID-19 vaccination policy, it is valid to offer a counter-perspective, not to debate the science but to validate the fact that those seeking exemptions were not espousing "bad science." These vaccines have a dangerous mechanism of action, in that they cause the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks, and now known for a longer period based on the late emergence of vaccine injury reports. This is unlike all other previous vaccine technologies where there is a set amount of antigen or live-attenuated virus. Specifically as it relates to Mrs. Gray, she is correct that these vaccines functional medically by hijacking the normal physiology – the one that her God gave her – and employing it to produce a foreign protein, thereby "altering" her from the image in which she was created.

For Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells causes the body's own immune system to attach to these organs. This is abundantly apparent with the large numbers of documented cases of myocarditis or heart inflammation among individuals below age 30 years.

Possible vaccine risks and side effects include myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. See Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L

Atmar, Clarence J Peters, Robert B Couch, Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus, https://pubmed.ncbi.nlm.nih.gov/22536382/; Centers for Disease Control and Prevention, Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020 (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm

`It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis. (McCullough PA, Philbin EF, Spertus JA, Kaatz S, Sandberg KR, Weaver WD; Resource Utilization Among Congestive Heart Failure (REACH) Study. Confirmation of a heart failure epidemic: findings from the Resource Utilization Among Congestive Heart Failure (REACH) study. J Am Coll Cardiol. 2002 Jan 2;39(1):60-9. https://www.sciencedirect.com/science/article/pii/S0735109701017004?via%3Dihub) In fact, The CDC held emergency meetings on COVID-19 vaccine-induced myocarditis and the FDA issued a warning on the Pfizer and Moderna vaccines for myocarditis. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021 In the cases reviewed by the CDC and FDA, 90% of children with COVID-19 induced myocarditis developed symptoms and clinical findings sufficiently severe to warrant hospitalization. https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-june-25-2021 Abu Mouch S, Roguin A, Hellou E, Ishai A, Shoshan U, Mahamid L, Zoabi M, Aisman M, Goldschmid N, Berar

Yanay N. Myocarditis following COVID-19 mRNA vaccination. Vaccine. May 2021. https://pubmed.ncbi.nlm.nih.gov/34092429/ Multiple studies and news reports detailed people 18-29 dying from myocarditis after receiving the COVID-19 vaccine. See FDA, Vaccines and Related Biological Products Advisory Committee June 10, 2021, Meeting Presentation, https://www.fda.gov/media/150054/download#page=17.

Another study found the post-second dose vaccination rates of cardiac adverse events among adolescent boys aged 12-15 was 162.2/million, which exceeded the rates reported by the CDC by 143-280% (2.4-3.8 times). Among boys aged 16-17, the estimate was 94.0/million, 31.5-41% higher than the CDC estimate. For girls 12-15 years old, the rate was 13.0/million, which was 43-100% higher than the CDC's estimate. Among girls 16-17, the estimate was 13.4/million, which was 47-65% higher than the CDC's estimate. Additionally, a follow up study found a 4-fold increased risk of post-vaccination myocarditis in those who had previously been infected with SARS-CoV-2. The Hoeg analysis demonstrates that for a young person, the risk of being hospitalized with vaccine-induced myocarditis is greater than the risk of contracting COVID-19 and later becoming hospitalized. Tracy Beth Høeg MD, PhD; Allison Krug, MPH; Josh Stevenson; John Mandrola, MD, SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis. August 2021. https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v2

The CDC announced that the vaccine is "likely linked" to myocarditis. Advisory Board, CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people, (June 24, 2021) https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation. There have been 6812 reported cases of myocarditis that have occurred, and the median age is thirty. https://www.openvaers.com/COVID-19-data (accessed Oct 4, 2021). These findings

suggest a markedly higher risk for myocarditis after COVID-19 injectable product use than for other known vaccines, and this is well above known background rates for myocarditis. COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing uncontrolled expression of SARS-CoV-2 spike protein within human cells. When one combines this fact with the temporal relationship of AE occurrence and reporting, biological plausibility of cause and effect, and the fact that these data are internally and externally consistent with emerging sources of clinical data, it supports a conclusion that the COVID-19 biological products are deterministic for the myocarditis cases observed after injection.

In October 2021, Sweden and Denmark announced they stopped the use of Moderna's COVID-19 vaccine for younger age groups due to cardiovascular side effects. The Swedish health agency said it would pause using the shot for people born in 1991 and later, as data pointed to an increase of myocarditis and pericarditis among youths and young adults that had been vaccinated. Denmark said that it had decided to pause giving the Moderna vaccine to people below 18 according to a "precautionary principle". https://news.yahoo.com/sweden-pauses-moderna-covid-vaccine-113809877.html

In the spring and summer of 2021, the FDA held multiple emergency meetings regarding the Janssen vaccine due to ongoing side effects. In April 2021, the CDC and FDA recommended a pause in the use of Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome. This complication causes a variety of stroke-like syndromes that can involve the cranial nerves, vision, and coordination. Blood clots in the venous sinuses of the brain are difficult to remove surgically and require blood thinners, sometimes with only partial recovery. In some cases, special glasses are required to correct vision and these young adults can be expected to miss considerable time away from school, undergoing neurological rehabilitation. This risk is not

predictable. https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-COVID-19-vaccine. Additionally, the FDA has an additional warning for Guillen-Barre Syndrome or ascending paralysis for the JNJ vaccine, which is not predictable and (when it occurs) can result in ascending paralysis, respiratory failure, the need for critical care, and death. Not all cases completely resolve, and some vaccine victims may require long term mechanical ventilation or become quadra- or paraplegics. Prolonged neurological rehabilitation is commonly required, and this will call for time away from school and studies for those children injured from the JNJ vaccine with Guillen-Barre Syndrome. https://www.fda.gov/media/150723/download In May 2022, the FDA further limited the use of the Janssen vaccine. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals

Notably, MLH's expert reports neglect to address any of these safety concerns in their reports, a disturbing fact at best and at worse a breach of medical ethics. They certainly must know that it is unethical to mandate – or even recommend – medical therapy without providing patients with Informed Consent that factually describes the risk / benefit of the treatment even for a EUA product. Furthermore, they most certainly know that no other vaccine in history has been supported by the FDA with the side effect profile of the Covid vaccines. Any other vaccine would have been withdrawn due to an unacceptable safety profile.

6. **Stem cells: Some individuals who challenged mandatory COVID vaccine policies raised religious objections based on stem cell use in testing/development of vaccines**

    a. Which stem cell lines were used in testing the COVID-19 vaccines available in September 2021?

    b. Other medicines for which stem cells were used in testing

Dr Salmon produced a list of medication and over-the-counter medication tested on HEK-293 cells or derivative cell lines. HEK-293 was isolated from a fetus in 1973. Aspirin was invented in 1897, Hydroxychloroquine was developed in 1955 and Ivermectin was discovered in 1975.

The Main Line experts challenge Mrs. Gray's understanding of how the Covid-19 vaccine can "alter" her genetically by stating that the vaccine is not gene therapy. From a religious perspective, they are ignoring her belief system while actually using incorrect technical information. At the time of the religious exemption request, the following information was readily available regarding the COVID-19 vaccines as "Gene Therapy" and should have been known by Main Line Health "experts":

First, Moderna, BioNTech, FDA, CDC have all historically described and classified mRNA products as "Gene Therapy." For example,

1. Moderna SEC Filing. Nov 9, 2018. Page 19. "Currently, mRNA is considered a gene therapy product by the FDA." https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/df2042b3-1071-4a4a-af1d-f6b0e9f9cbd3.pdf
2. Moderna SEC Filing. Aug 2020. Page 69. https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/dfd10d54-ff56-40f1-b2e6-c4fc887b6afc.pdf "As a potential new class of medicines, no mRNA medicines have been approved to date by the FDA or other regulatory agency. Successful discovery and development of mRNA medicines by either us or our strategic collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. We have made and will continue to make a series of business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology, and manufacturing processes, which may be shown to be incorrect based on further work by us, our strategic collaborators, or others.

Prior to the Phase 3 trial for mRNA-1273 and that of one other company, there had never been a Phase 3 trial in which mRNA is the primary active ingredient, and there has never been and there may never be a commercialized product in which mRNA is the primary active ingredient. Our mRNA investigational medicines that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds, or fail to reach the market for many reasons."

3. BioNTech SEC Filing. Sept 2019. Page 21. "mRNA therapies have been classified as gene therapy medicinal products" https://investors.biontech.de/static-files/3f09b9d5-ef02-42bc-8dc4-b2fd6090d8dc

4. FDA Guidance Document Titled: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products https://www.fda.gov/media/89036/download Footnote #1: "Gene therapy products are all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms. The products may be used to modify cells in vivo or transferred to cells ex vivo before administration to the recipient."

5. FDA has described "Gene Therapy" as "Human gene therapy that seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. Gene therapy is a technique that modifies a person's genes to treat or cure disease. Gene therapies can work by several mechanisms:

- Replacing a disease-causing gene with a healthy copy of the gene
- Inactivating a disease-causing gene that is not functioning properly
- Introducing a new or modified gene into the body to help treat a disease"

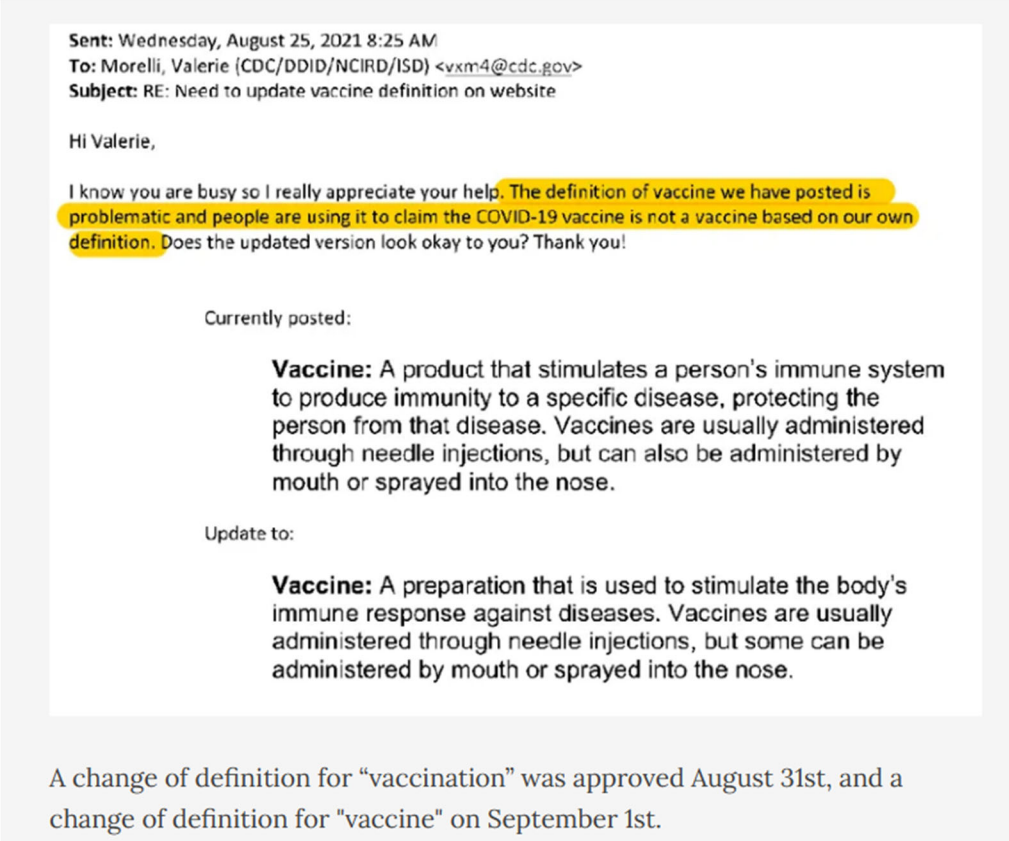
https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

a. The mRNA in the COVID shots are molecules that contain genetic instructions for making various proteins. mRNA COVID shots deliver synthetic mRNA with a genetic code that instructs cells to produce a modified form of the SARS-CoV-2 spike protein. In other words, they "alter the biological properties of living cells for therapeutic use." The FDA's definition of "Gene Therapy" uses the word "or" in the definition. Gene therapy can alter gene expression OR it may alter alter the biologic properties of living cells for therapeutic use. Both explanations qualify as gene therapy per the FDA's definition. Mrs, Gray's religious objection to the use of such products is clearly consistent with her refusing manipulative therapy for conception purposes.

b. The FDA's guidance for the human gene therapy products industry also classified mRNA injections as gene therapy. Importantly, the FDA stressed that gene therapy products that carry microRNA or cytokines can have "unknown pleotropic effects, including altered expression of host (human) genes that could result in unpredictable and undesirable outcomes. https://www.fda.gov/media/113768/download?attachment

c. When the Covid vaccines were introduced in early 2021, the products did not meet the CDC's definition of a vaccine, so the CDC changed the definition of a vaccine. Until the end of October 2021, the CDC defined a vaccine as "a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease." Immunity, in turn, was defined as "protection from an infectious disease," meaning that "If you are immune to a disease, then you can be exposed to it without becoming infected." The new definition of "vaccine" is: "A

preparation that is used to stimulate the body's immune response against diseases." So, a "vaccine" went from being something that produces protective immunity, to simply stimulating an immune response. The key words "to produce immunity" were eliminated from the equation. These changes allow the COVID shots to fit the new description. Covid-19 vaccination does not grant immunity and weren't designed to prevent infection in the first place. Internal CDC correspondence, obtained through Freedom of Information Act (FOIA) requests, conclusively proves the reason for the change was simply to shut down arguments by "right-wing COVID-19 pandemic deniers" that "COVID-19 vaccines are not vaccines per CDC's own definition." Nov 2021. Why Did the CDC Quietly Change Its Definition Of 'Vaccine' For New COVID Shots? https://www.thepulse.one/p/why-did-the-cdc-quietly-change-its-definition-of-vaccine-for-new-covid-shots



Sent: Wednesday, August 25, 2021 8:25 AM
To: Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>
Subject: RE: Need to update vaccine definition on website

Hi Valerie,

I know you are busy so I really appreciate your help. The definition of vaccine we have posted is problematic and people are using it to claim the COVID-19 vaccine is not a vaccine based on our own definition. Does the updated version look okay to you? Thank you!

Currently posted:

Vaccine: A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.

Update to:

Vaccine: A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.

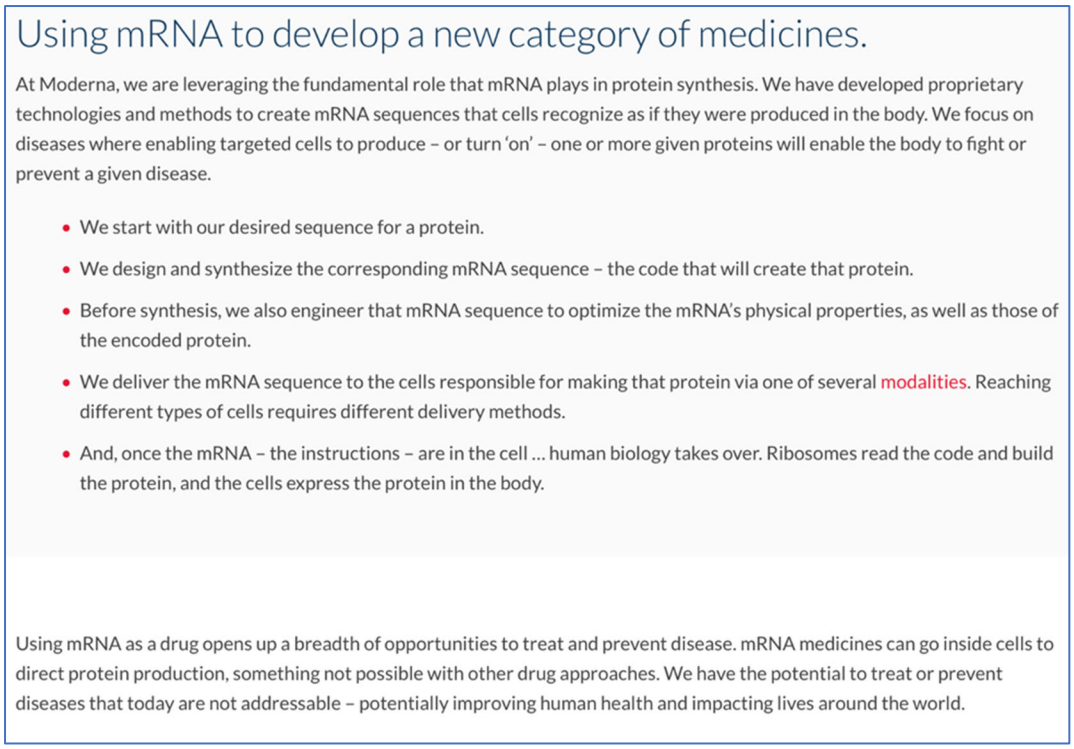
A change of definition for "vaccination" was approved August 31st, and a change of definition for "vaccine" on September 1st.

6. The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines," or vaccines produced from gene therapy molecular platforms which, according to US FDA regulatory guidance, are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. FDA. Food and Drug Administration. (Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance for Industry. FDA-2018-D-2173. 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products). The FDA has "advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product, specifying that the long-term follow-up observation should include a minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire." The administration of the Moderna, Pfizer, and JNJ vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up, which were not offered in the United States. See EUA briefing documents for commitments for to follow up: Moderna, Pfizer, J&J. https://www.fda.gov/media/144434/download , https://www.fda.gov/media/144245/download , https://www.fda.gov/media/146219/download

7. Previously, Moderna's website described the genetic aspect inherent in mRNA products: "mRNA medicines are sets of instructions. And these instructions direct cells in the body to make proteins to prevent or fight disease. Messenger ribonucleic acid, or mRNA for short, plays a vital role in human biology, specifically in a process known as protein synthesis.

mRNA is a single-stranded molecule that carries genetic code from DNA in a cell's nucleus to ribosomes, the cell's protein-making machinery." "mRNA medicines are sets of instructions. And these instructions direct cells in the body to make proteins to prevent or fight disease." https://www.modernatx.com/mrna-technology/science-and-fundamentals-mrna-technology

Below is a previous screenshot from Moderna website.



Using mRNA to develop a new category of medicines.

At Moderna, we are leveraging the fundamental role that mRNA plays in protein synthesis. We have developed proprietary technologies and methods to create mRNA sequences that cells recognize as if they were produced in the body. We focus on diseases where enabling targeted cells to produce – or turn 'on' – one or more given proteins will enable the body to fight or prevent a given disease.

- We start with our desired sequence for a protein.
- We design and synthesize the corresponding mRNA sequence – the code that will create that protein.
- Before synthesis, we also engineer that mRNA sequence to optimize the mRNA's physical properties, as well as those of the encoded protein.
- We deliver the mRNA sequence to the cells responsible for making that protein via one of several modalities. Reaching different types of cells requires different delivery methods.
- And, once the mRNA – the instructions – are in the cell … human biology takes over. Ribosomes read the code and build the protein, and the cells express the protein in the body.

Using mRNA as a drug opens up a breadth of opportunities to treat and prevent disease. mRNA medicines can go inside cells to direct protein production, something not possible with other drug approaches. We have the potential to treat or prevent diseases that today are not addressable – potentially improving human health and impacting lives around the world.

8. March 2021. Doerfler. Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based Covid-19 Vaccines: Possible Integration into the Human Genome - Are Adenoviral Genes Expressed in Vector-based Vaccines? "Adenovirus particles likely are taken up by cells of the lymphatic system and the liver, and their DNA will be transported to the cells' nuclei. In this review, the evidence for insertion of adenovirus DNA into recipient genomes and its consequences has been presented." https://www.sciencedirect.com/science/article/pii/S0168170221001738?via%3Dihub

9. April 2021. Zhang. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. "SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell and be expressed as chimeric transcripts fusing viral with cellular sequences. Importantly, such chimeric transcripts are detected in patient-derived tissues." https://doi.org/10.1073/pnas.2105968118
10. September 2015, Weissman and Kariko titled their article in Molecular Therapy "mRNA: Fulfilling the Promise of Gene Therapy". This is one of many examples of how mRNA was historically described, prior to negative fallout about the concept of "gene therapy" in the court of public opinion. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4817894/
11. May 2017. Pardi et al. "mRNA vaccines – a new era in vaccinology" Nature Reviews in Drug Discovery. No mRNA vaccine had moved beyond Phase 2 clinical trials. Never had the FDA approved an mRNA vaccine. https://www.nature.com/articles/nrd.2017.243

Table 2 | **Clinical trials with mRNA vaccines against infectious diseases**

Sponsoring institution	Vaccine type (route of administration)	Targets	Trial numbers (phase)	Status
Argos Therapeutics	DC EP with autologous viral Ag and CD40L mRNAs (i.d.)	HIV-1	• NCT00672191 (II) • NCT01069809 (II) • NCT02042248 (I)	• Completed[105] • Completed; results NA • Completed; results NA
CureVac AG	RNActive viral Ag mRNA (i.m., i.d.)	Rabies virus	NCT02241135 (I)	Active[56,91]
Erasmus Medical Center	DC loaded with viral Ag mRNA with TriMix (i.nod.)	HIV-1	NCT02888756 (II)	Recruiting
Fundació Clínic per la Recerca Biomèdica	Viral Ag mRNA with TriMix (NA)	HIV-1	NCT02413645 (I)	Active
Massachusetts General Hospital	DC loaded with viral Ag mRNA (i.d.)	HIV-1	NCT00833781 (II)	Completed[104]
McGill University Health Centre	DC EP with autologous viral Ag and CD40L mRNAs (i.d.)	HIV-1	NCT00381212 (I/II)	Completed[102]
Moderna Therapeutics	Nucleoside-modified viral Ag mRNA (i.m.)	Zika virus	NCT03014089 (I/II)	Recruiting[85]
		Influenza virus	NCT03076385 (I)	Ongoing[22]

The table summarizes the clinical trials registered at ClinicalTrials.gov as of 5 May 2017. Ag, antigen; CD40L, CD40 ligand; DC, dendritic cell; EP, electroporated; i.d., intradermal; i.m., intramuscular; i.nod., intranodal; NA, not available.

12. As reported in Molecular Therapy in April 2019, still no mRNA vaccine had moved beyond Phase 2 clinical trials. Never had the FDA approved an mRNA vaccine. Maruggi, Giulietta et al. "mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6453507/pdf/main.pdf

Table 4. mRNA Vaccines for Infectious Diseases in Clinical Trials

Sponsor	Indication	mRNA Vaccine: Delivery	Trial No. (ClinicalTrials.gov)	Stage	Status and References
CureVac	rabies	CV7201 (sequence-optimized mRNA: protamine-RNA)	NCT02241135	phase I	completed[75] PCD: February 2018
CureVac	rabies	CV7202 (sequence-optimized mRNA: LNPs)	NCT03713086	phase I	recruiting[160] PCD: December 2019
Moderna	influenza H10N8	mRNA-1440 (nucleoside-modified mRNA: LNPs)	NCT03076385	phase I	completed[71] PCD: October 2018
Moderna	influenza H7N9	mRNA-1851 (nucleoside-modified mRNA: LNPs)	NCT03345043	phase I	active PCD: September 2018
Moderna	hMPV/HPIV3	mRNA-1653 (nucleoside-modified mRNA: LNPs)	NCT03392389	phase I	active PCD: July 2019
Moderna	Zika	mRNA-1325 (nucleoside-modified mRNA: LNPs)	NCT03014089	phase I/II	active PCD: September 2018
Moderna	HCMV	mRNA-1647 and mRNA-1443 (nucleoside-modified mRNA: LNPs)	NCT03382405	phase I	recruiting PCD: February 2020
Moderna	chikungunya	mRNA-1388 (nucleoside-modified mRNA: LNPs)	NCT03325075	phase I	active PCD: March 2019

The table summarizes clinical trials that evaluate vaccination by direct injection of mRNA vaccines registered at ClinicalTrials.gov as of January 8, 2018. Clinical evaluation of vaccination with dendritic cells loaded with antigen-expressing mRNAs is reviewed elsewhere.[169] HCMV, human cytomegalovirus; hMPV, human metapneumovirus; HPIV3, human parainfluenza virus type 3; LNP, lipid nanoparticle; Moderna, Moderna Therapeutics; PCD, estimated primary completion date; Ref., References.

13. April 2019. Cell. mRNA as a Transformative Technology for Vaccine Development to Control Infectious Diseases. "It is still too early to fully understand its safety and effectiveness in humans. Recently published results from two clinical trials of conventional mRNA vaccines against infectious diseases showed an overall good tolerability profile and promising immunogenicity, but with more modest responses than expected based on results from animals." "Several questions remain unanswered, including the relative utility of nucleoside-modified versus unmodified mRNAs, self-amplifying mRNAs versus conventional mRNAs, the most efficient and safest delivery system, and the best route of administration. In addition, the safety and tolerability profile of these emerging technologies needs to be fully elucidated." https://www.cell.com/action/showPdf?pii=S1525-0016%2819%2930041-3

Since some support for the COVID-19 vaccine technology was based upon Adenovirus Vaccine work, a description from the NY Times is relevant:

a. "The researchers added the gene for the coronavirus spike protein to another virus called Adenovirus 26."

b. "After the vaccine is injected into a person's arm, the adenoviruses bump into cells and latch onto proteins on their surface. The cell engulfs the virus in a bubble and pulls it

inside. Once inside, the adenovirus escapes from the bubble and travels to the nucleus, the chamber where the cell's DNA is stored."

c. "The adenovirus pushes its DNA into the nucleus. The adenovirus is engineered so it can't make copies of itself, but the gene for the coronavirus spike protein can be read by the cell and copied into a molecule called messenger RNA, or mRNA."

d. https://www.nytimes.com/interactive/2020/health/johnson-johnson-covid-19-vaccine.html

14. Further from the NY Times:

a. "Like the Pfizer-BioNTech vaccine, Moderna's vaccine is based on the virus's genetic instructions for building the spike protein."

b. "The vaccine uses messenger RNA, genetic material that our cells read to make proteins."

c. "After injection, the vaccine particles bump into cells and fuse to them, releasing mRNA. The cell's molecules read its sequence and build spike proteins."

d. https://www.nytimes.com/interactive/2020/health/moderna-covid-19-vaccine.html

15. Tamseel Fatima in "What Why and How of mRNA Vaccines" Feb 2021. "RNA vaccines exploit the gene expression mechanism of the cell. The vaccine consists of mRNA encoding the antigen. Once inside the cell the mRNA is translated into the antigens, which is equivalent to hijacking the cells. The antigens are displayed on the cell surface and are recognized by the immune system." "Although, the first successful in-vivo gene therapy that used mRNA was reported in 1990, it took three decades of research until the first mRNA vaccine was available. The main challenges on the development road are delivery and the poor stability of mRNA. The mRNA molecule is highly susceptible to degradation by the immune system." "In

order to produce an mRNA vaccine, the DNA sequence of the desired gene (coding for the antigen) is transcribed. This mRNA is then modified by adding untranslated regions (UTRs), a 5' cap and a 3' polyA tail. This way, the synthetic mRNA mimics the host cell's mRNA." https://the-dna-universe.com/2021/02/18/what-why-and-how-of-mrna-vaccines/

16. Tamseel Fatima and Dr. Andreas Ebertz in "The history of mRNA applications" April 2021. "Fundamentally, mRNA therapeutics can be considered as a transient form of gene therapy that bypasses the complications of "conventional" gene therapy where DNA is inserted in the genome, including insertional mutagenesis and toxicity associated with viral vectors." https://the-dna-universe.com/2021/04/15/the-history-of-mrna-applications/

17. Definition of a "gene" from Merriam Webster: "a specific sequence of nucleotides in DNA or RNA that is located usually on a chromosome and that is the functional unit of inheritance controlling the transmission and expression of one or more traits by specifying the structure of a particular polypeptide and especially a protein or controlling the function of other genetic material." https://www.merriam-webster.com/dictionary/gene#:~:text=%3A%20a%20specific%20sequence%20of%20nucleotides,or%20controlling%20the%20function%20of

18. The definition of "mRNA" from Wikipedia describes mRNA as a genetic sequence; therefore, mRNA is inherently "genetic therapy". "In molecular biology, messenger ribonucleic acid (mRNA) is a single-stranded molecule of RNA that corresponds to the genetic sequence of a gene, and is read by a ribosome in the process of synthesizing a protein." "As in DNA, genetic information in mRNA is contained in the sequence of nucleotides." https://en.wikipedia.org/wiki/Messenger_RNA.

Religious foundations based upon a belief of the individual being created in the image of God that view the COVID-19 vaccine as an unnatural process or one that alters this image cannot be discounted as representing "bad science." In fact, to do so, is to be intellectually dishonest.

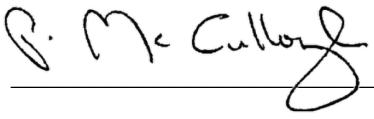
Summary: Counter points to Dr Salmon's summary

Dr. Salmon asserts several misleading and inaccurate comments in his summary. These are identified in italics below.

- Health care staff were disproportionately impacted by COVID-19 and patients in health care settings were at increased risk of serious disease and death because of underlying health conditions and/or age. *Robust evidence showed that SARS-CoV-2 was mostly likely to spread at home. Further, spread was driven primarily by symptomatic people. It was also widely known that vaccinated people were indeed unwittingly spreading the virus.*
- There were three vaccines approved for use at the time, and they had been shown to be very safe and effective at preventing diseases, reducing transmission of disease, and serious consequences from COVID-19 including death. *It is not accurate to say that the vaccines were very safe. Safety concerns were beginning to emerge and were widely documented. In addition, efficacy greatly reduced by the three month mark. Interestingly, the FAQ document that Main Line Health published claimed that mRNA vaccines have a long history of safety despite not a single one being FDa approved for marketing at the time it was published.*
- Consequently, unvaccinated persons in health care settings were at greater risk of COVID-19 themselves, and posed risk to others they came into contact with. *There is no evidence that unvaccinated persons posed any greater risk than vaccinated persons.*

- While many health care workers had already been infected at this time, natural immunity was poorly understood and not a substitute for vaccination. *This statement is not true. Natural immunity was already shown to be effective against preventing future disease and was a completely logical and scientifically justified substitute for vaccination.*
- However, these health care institutions needed to limit exemptions to those persons with sincerely held religious beliefs that precluded vaccination in order to protect their staff and patients. *There is no objective way to do this and therefore Main Line Health created subjective tests based upon its indefensible science positions.*
    - Easily granting religious exemptions to all persons who requested them would have undermined the vaccine requirement leading to substantial disease, disability and death among health care staff and patients. *If MLH had granted religious exemptions to every single person who applied for exemption, MLH could have still achieved extremely high vaccination levels. Religious exemptions were requested by less than 1% of all MLH staff. This would not have undermined the vaccine requirement, nor led to substantial disease, disability, and death.*

I reserve my right to amend and modify these opinions based upon further information that is presented by Main Line Health's experts regarding their positions.



Date: September 19, 2023

Peter A. McCullough, MD

EXHIBIT B

Expert Report of Akram Boutros, MD, FACHE

Professional Experience

Dr. Boutros is a Professor of Clinical Medicine at Case Western Reserves University School of Medicine and is a seasoned hospital and health system executive.

Dr. Boutros is broadly trained in internal medicine. Dr. Boutros received a Bachelor of Science (BS) in Biology and Chemistry from St. John's University in 1983. He received his MD from State University of New York, Downstate Medical Center in 1988. He is a graduate of the Harvard Business School Advanced Management Program in 2005.

Dr. Boutros has held positions in clinical and academic medicine. He has over 30 years of experience in medical staff affairs, quality improvement, patient safety, and healthcare management. Dr. Boutros's current curriculum vitae is attached (Appendix 1).

Dr. Boutros has been retained by John Daller, MD, Esq. Dr. Boutros has reviewed the Deposition of Dawn Gray, MSN, RN, CEN, CCRN of July 12, 2023, in Civil Action No. 2-23-CV-00363-KNS, and testimony Expert Report of Daniel Salmon, Ph.D., MPH.

The client has not impacted the content of this report. All opinions herein are those of Dr. Boutros. Dr. Boutros has been compensated at a rate of $400 per hour for time spent preparing this report.

The Plaintiff requested Dr. Boutros to provide opinions on Dawn Gray, MSN, RN, CEN, CCRN Covid-19 Vaccine Religious Exemption Request, and Expert Report of Daniel Salmon, Ph.D., MPH.

Ms. Gray "gave her life to Jesus at the age of five at Vacation Bible School." She is a member New Story Church, a nondenominational church, whose members' "beliefs is that we use the Bible as a source of truth, and we circle back and we make decisions and follow the Lord according to the truth that is in the Bible."

Ms. Gray submitted a Final Appeal Exemption Form on September 27, 2021, after her initial religious exemption request was denied. She testified that she has long held belief that use of any genetic material, especially those that were obtained or could have been obtained from aborted fetuses, is an alteration of God's plan and image.

Ms. Gray clearly testified that her experience with infertility was an important basis for her contemplation of her faith and relationship with God. It is her firmly held belief that exogenous manipulation of genetic material, (i.e., in-vitro fertilization) is an alteration of God's plan and image. This is critical to understanding her beliefs because she was opposed to alterations of her own genetic material, not just foreign genetic material.

In her testimony, she draws equivalency of this type of manipulation of her own genetic material and the COVID vaccine's introduction of foreign genetic material as an alteration of God's plan and image.

In addition, despite Ms. Gray's polyethylene glycol (PEG) allergy, which is in itself a reason for a COVID vaccine exemption, she clearly focused on her religious beliefs as the most important reason to receive the exemption.

In September 2021, PEG had never been used before in an approved vaccine as it was in the Pfizer, BioNTech, and Moderna messenger RNA (mRNA) for packaging the vaccine's main ingredient. PEG is found in many drugs that have occasionally triggered anaphylaxis. Anaphylaxis is a potentially life-threatening reaction that can cause extremely low blood pressure, shortness of breath, and tachycardia. Allergists and immunologists have reported that some people previously exposed to PEG may have elevated levels of antibodies against PEG, putting them at risk of an anaphylactic reaction to the COVID vaccine. As early as December 2020, at least eight people were noted to have this severe allergic reaction after receiving the COVID-19 vaccine.

It is important to note the above facts, as majority of health systems across the country instituted mandatory COVID-19 vaccine policies, they permitted both medical and religious exemptions, and achieved similar of lower rates of staff COVID-19 infections to hospitals and health systems that permitted very few exemptions.

Religious beliefs are hard for businesses to evaluate because no individual, panel of experts, or institution can create a litmus test for what is in someone's heart or head. Consequently, most hospitals and health systems opted for processes that were fairly communicated, and universally applied to provide the exemptions.

In September 2021, it was also clear that institutions that allowed a larger number of exemptions did not experience larger number of staff or community infections.

In summary, the draconian denial of religious exemption by Main Line Hospitals in this case is severe, egregious, and unreasonable compared to most health system and

hospitals in the United States. This is based on discussions with hospital and health system leaders throughout 2020 and 2021, as well as our experience at The MetroHealth System.

Dr. Salmon, in his report responds to the following questions, which are mostly irrelevant to this case. In addition, his answers offer the reader a biased and unbalanced view of the science related to COVID-19 transmission in healthcare settings. As such, I will only address the issues specific to the denial of religious exemption in healthcare settings.

1. Covid threat to patients and employees in September 2021
    a. In September 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?
    b. How did asymptomatic transmission impact the spread of COVID-19 in health care facilities?
    c. Was exposure to COVID-19 in health care setting an occupational hazard for employees?
    d. What was the impact of COVID-19 on health care system, patient access to care and care quality?
    e. Why were health care personnel high priority group (#1a) when vaccines had limited availability?

2. Safety and Efficacy of COVID-19 Vaccines
    a. What was the efficacy of vaccines available in September 2021?
    b. In September 2021 were unvaccinated persons at an increased risk of contracting COVID and transmitting it to others who could not be vaccinated because of medical contraindications, were too young to be vaccinated or for whom the vaccine was not effective?

    c. In September 2021, did the science indicate that “natural immunity” was as effective as vaccination?

3. Justification for mandatory Covid vaccine policy by health care institutions
    a. September 2021, did Covid-19 pose a direct threat to patients and staff in health care facilities?
    b. In September 2021, were mandatory COVID-19 vaccine policies a critical protective action for health care institutions to protect patients and staff?
    c. Did anticipation of the upcoming flu season justify rollout of mandatory COVID-19 vaccine policy in September 2021?

   d. Did mandatory COVID-19 vaccine policies pose risk that health care workers would choose to leave job rather than get vaccinated?
   e. How did mandatory COVID-19 vaccine policies impact vaccine hesitancy?

4. Impact of medical and religious exemption requests on health care institutions
   a. What were the clinical contraindications to receiving the COVID vaccine?
   b. How did non-medical vaccine exemption requests impact the efficacy of vaccine requirements and patient safety?
   c. Did exemptions seriously undermine the efficacy of a vaccination requirement?
   d. Did health care institutions have a responsibility to patients and staff to establish and implement a process for evaluating exemption requests rather than simply rubber-stamping requests?
   e. How did exemptions impact the operations of the health care institutions?
   f. How effective were alternative infection control strategies (masking, testing, social distancing) in health care institutions?

5. Anti-vaccine movement's impact on mandatory vaccine policies
   a. Was there an anti-vax movement that impacted COVID-19 vaccine hesitancy in September 2021?
   b. What is the impact of the anti-vaccine movement on mandatory vaccine policies?

6. Stem cells: Some individuals who challenged mandatory COVID vaccine policies raised religious objections based on stem cell use in testing/development of vaccines
   a. Which stem cell lines were used in testing the COVID-19 vaccines available in September 2021?
   b. Other medicines for which stem cells were used in testing

Dr. Boutros's professional judgement in these areas is based upon review of current scientific evidence and current information available of the impact of religious exemptions and masking on the spread of COVID-19.

Justification for mandatory Covid vaccine policy by health care institutions

As of September 2021, did Covid-19 pose a direct threat to patients and staff in health care facilities?

While Dr. Salmon of appropriately notes that “as of September 2021, COVID-19 posed a direct threat to patients and staff in health care facilities,” and that “health care facilities around the country and the world were being overwhelmed by COVID-19,” he fails to recognize that the overwhelming majority of COVID-19 cases in patients and staff in healthcare facilities were as a result of community transmission. He notes that “health care staff were disproportionately impacted by COVID-19,” but fails to point out that a substantial portion of the United States populous were working from home, learning from home, and restricted their travel significantly. Hospitals throughout the country took significant precautionary measures to reduce the risk of transmission in health care settings, and these measures were applied equally to vaccinated and unvaccinated patients and staff.

As of September 2021, were mandatory COVID-19 vaccine policies a critical protective action for health care institutions to protect patients and staff?

Dr. Salmon notes that “as of September 2021, mandatory COVID-19 vaccine policies were a critical protective action for health care institutions to protect patients and staff.” He fails to mention that mandatory vaccination policies have always had exemptions for medical and religious reasons. He also fails to mention that the goal of mandatory vaccination is to achieve herd immunity, which has been consistently noted to be vaccination levels above eighty percent of the select group.

It is important to note the above facts, as we instituted mandatory COVID-19 vaccine policies at The MetroHealth System, and we permitted both medical and religious exemptions, and achieved similar of lower rates of staff COVID-19 infections to hospitals and health systems that permitted very few exemptions.

Did anticipation of the upcoming flu season justify rollout of mandatory COVID- 19 vaccine policy in as of September 2021?

While there were fears of co-epidemics of COVID-19 and influenza, there were no scientific or CDC recommendation to reject medical and religious exemptions, or that such exemptions would pose a higher risk of transmission to the patient or staff in healthcare settings.

In the 2020-21 influenza season, prevalence of influenza was low in the United States and globally due to control measures already in place to limit COVID-19 transmission.

Dr. Salmon notes that “many healthcare institutions require influenza vaccination among their workers to protect their employees and the patients they care for, and that “The Society for Healthcare Epidemiology of America (SHEA) strongly endorses mandatory vaccination of healthcare workers to protect against influenza,” but again he fails to note that these recommendations allow for medical and religious exemptions.

Did mandatory COVID-19 vaccine policies pose risk that health care workers would choose to leave job rather than get vaccinated?

Healthcare CEOs were concerned that health care workers may choose to leave their job rather than get vaccinated at a time when patients were overwhelming hospital capacity. This would pose a health care crisis of great proportion. The inability to provide adequate care to patients in an appropriate acute care setting has catastrophic effect on individual care and the care of the entire community.

How did mandatory COVID-19 vaccine policies impact vaccine hesitancy?

Dr. Salmon appropriately notes that “mandatory COVID-19 policies likely had a mixed impact on vaccine hesitancy.” While most healthcare workers supported or acquiesced to the policy, it prompted more staff to request exemptions from COVID-19 and Influenza.

What were the clinical contraindications to receiving the COVID vaccine?

Dr. Salmon appropriately notes that accepted contraindications for receiving COVID-19 vaccines are histories of severe allergic reaction to a previous dose or to a component of the COVID-19 vaccine.

How did non-medical vaccine exemption requests impact the efficacy of vaccine requirements and patient safety?

Dr. Salmon appropriately notes that unvaccinated persons are at increased risk of contracting disease and transmitting disease to others. He focused on the impact of those who were unvaccinated by choice on those who have a medical contraindication to the vaccine. He fails to mention that the reason for being unvaccinated is irrelevant as the virus does not cause a higher degree of transmission because someone received a religious exemption versus someone who is unvaccinated due to medical contraindications.

Because there are no studies on the impact of non-medical exemptions on COVID-19 transmission, he relies on studies of pertussis and measles among children. These are different viruses, with different epidemiological characteristics. His argument that these studies are consequential to the issue of granting COVID-19 vaccination exemptions is pure conjecture.

The Measles virus is one of the most contagious viruses studied. If one person is infected with Measles, up to 90% of the people close to that person who are not immune will also become infected. That is not the case for COVID-19 transmission.

How did exemptions impact the operations of the health care institutions?

Dr. Salmon appropriately notes that "exemptions to vaccine mandates had a substantial impact on the operations of the health care institutions." Health care institutions had to develop processes for granting medical exemptions and religious exemptions. Both types of exemptions required the development of fair processes to assess the employees' requests and criteria for granting or denying requests. In addition, depending on the rate of COVID-19 transmission in the community and the demand for hospital services, hospital administrators had to weigh the impact of increasing COVID-19 vaccinations by a few percentage points (most institutions achieved vaccination rates well over 80%) with the need for skilled healthcare worker.

Did health care institutions have a responsibility to patients and staff to establish and implement a process for evaluating exemption requests rather than simply rubber-stamping requests?

Dr. Salmon appropriately notes that "health care institutions had a responsibility to limit religious exemptions to those with sincerely held beliefs that precluded vaccination in order to protect their staff and patients." The manner by which institutions evaluated the exemptions varied widely. He also states that the greater the number of exemptions the higher the risk of infections and transmission. While this is true, it is most profound when exemptions constitute a meaningful percentage of the staff. The infringement on staff's religious beliefs has the potential to reduce the number of necessary healthcare professionals needed to care for the community and negatively impact the work environment.

Do exemptions from a mandatory vaccination policy undermine an organization's ability to inhibit the spread of a serious communicable disease?

Exemptions from mandatory vaccination policy have not been found to undermine healthcare institutions' ability to inhibit the spread of a serious communication disease. The use of both medical and religious exemptions for Influenza vaccination is widespread throughout the healthcare industry.

How effective were alternative infection control strategies (masking, testing, social distancing) in health care institutions?

In September 2021, alternative infection control strategies such as masking, testing and social distancing were recommended for both patients and staff who could not or would not be vaccinated against COVID-19. With over 80% of staff being vaccinated, the small number of exemptions that healthcare institutions allowed, did not pose additional risk to patients, staff of the healthcare institutions, nor the community.

Because COVID-19 is primarily spread through droplet inhalation, mask wearing in health care settings was universally recommended to control the spread of COVID-19. Healthcare institutions, such as The MetroHealth System, which issued both medical and religious exemption did not experience higher rates of staff infections. I am also unaware of any studies that demonstrated any differences in COVID-19 infection rates at healthcare institutions that issued larger numbers of exemptions than those issued smaller numbers of exemptions.

In addition, social distancing reduces the transmission of COVID-19 in healthcare settings. In September of 2021, many health care facilities assigned COVID-19 patients to specific nursing units.

As importantly, vaccination did not confer 100% immunity, and did not always protect against the spread of COVID-19. In some cases, vaccinated staff were less compliant with masking, handwashing, and social distancing because they falsely believed they were 100% immune.

Summary

In September 2021, COVID-19 spread was of significant concern to the entire community. Healthcare executives were routinely evaluation the impact of deterrents to spread, such as vaccination, handwashing, social distancing, and masking on the care of the patients, the healthcare staff, and the community.

Understaffed hospitals were appropriately concerned about losing staff due to mandatory COVID-19 vaccination programs. Most organization provided processes to permit religious exemption requests, while remaining compliance with the Centers for Medicare & Medicaid Services 100% mandatory vaccination rule.

Non-Medical Exemptions, Including (Religious) Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospital's policies and procedures. We direct hospitals to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (https://www.eeoc.gov/laws/guidance/section12-religious-discrimination) for information on evaluating and responding to such requests.

Note: Surveyors will not evaluate the details of the request for a religious exemption, nor the rationale for the hospital's acceptance or denial of the request. Rather, surveyors will review to ensure the hospital has an effective process for staff to request a religious exemption for a sincerely held religious belief.

The Center for Medicare and Medicaid Services has provided rules for facilities to comply with the Conditions of Participation. They require 100% of the staff to be fully vaccinated against COVID-19, except for those who have medical or religious reasons to request exemption. They specifically state:

> **Accommodations of Unvaccinated Staff with a Qualifying Exemption:**
> While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodation can be addressed in the hospital's policies and procedures.
>
> Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see

> CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.
>
> Regulatory Provisions implemented 60 days after issuance of this memorandum: Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations.

I have reviewed the Hybrid Witness Disclosure of Drs. Stallkamp and Gilbert. Much of the topics of their testimony is covered in Dr. Salmon's Expert Witness Report. While I agree with much of the testimony described in the Hybrid Witness Disclosures, I am unconvinced that Dr. Stallkamp testimony to the need for the robust Policy mandate causes operational hardships imposed by exemptions and alternatives to vaccination. To the contrary, not providing medical and religious exemptions to the COVID-19 vaccination mandate increases the risk to the community by reducing the number of healthcare professionals available to care for a community in need.

His view that "any exemptions to the Policy mandate gave rise to significant (more than de minimis) operational hardships," is not what responsible and reasonable healthcare executives hold as factual.

Most healthcare institutions required employees to request exemptions for "sincerely held religious beliefs." Employees were requested to provide statements detailing their opposition to the vaccine because of religious reasons, as opposed to political or personal.

Religious beliefs are hard for businesses to evaluate because no individual, panel of experts, or institution can create a litmus test for what is in someone's heart or head. Consequently, most healthcare opted for processes that were fairly communicated, and universally applied to provide the exemptions.

In addition, COVID-19 vaccinated staff were still being infected and reducing the number of professional staff to care for the surge of patients. Staff that were provided medical and religious exemptions effectively utilized the same alternative control measures (social distancing, handwashing, and masking) to control spread of COVID-19.

Finally, institutions that allowed a larger number of exemptions did not experience larger number of staff or community infections.

9/2/2023

Akram Boutros, MD

ACADEMIC CURRICULUM VITAE

GENERAL INFORMATION

Name:	Akram Boutros, M.D., FACHE
Office Telephone:	(216) 304-8440
Office Email:	akram@akramboutros.com
Home Address:	1684 Lorain Avenue Cleveland, Ohio 44113
Cellular Telephone:	516-567-8897
Citizenship:	United States of America
Birthdate:	February 5, 1962
Birth Place:	Cairo, Egypt
Marital Status	Married
Military Service:	None

EDUCATION

University:	Saint John's University, Jamaica, New York B.S., Chemistry and Biology - Magna Cum Laude Sep 1979 - Jun 1983
Medical Education:	SUNY - Downstate Medical Center, Brooklyn, New York Medical Doctor - Distinction in Research Sep 1983 - May 1988
Business School:	Harvard Business School, Cambridge, Massachusetts Advanced Management Program 2005
Additional Education:	Hofstra University, Hempstead, New York M.S. in Research in Education and Program Evaluation (incomplete) Sep, 1993 - Jun 1994

POSTGRADUATE TRAINING

Internship:	Winthrop University Hospital, Mineola, New York Internal Medicine Jul 1988 - Jun 1989

POSTGRADUATE TRAINING (Continued)

Residency:	Winthrop University Hospital, Mineola, New York Internal Medicine Jul 1989 - Jun 1991
Chief Residency:	Winthrop University Hospital, Mineola, New York Internal Medicine Jul 1991 - Jun 1992

FACULTY & ACADEMIC APPOINTMENTS

Assistant Clinical Instructor	Stony Brook University's School of Medicine, Stony Brook, New York Department of Medicine Jul 1991 - Jun 1992
Instructor	Stony Brook University's School of Medicine, Stony Brook, New York Department of Medicine Jul 1992 - Sep 1994
Assistant Professor	Stony Brook University's School of Medicine, Stony Brook, New York Department of Medicine Oct 1994 - June 1999
Guest Lecturer	Harvard Business School, Cambridge, Massachusetts Advanced Management Program Sep 2006 - May 2007
Guest Lecturer	The School of Business at Adelphi University, Garden City, New York Masters in Business Administration Program Sep 2007 - Jun 2010
Guest Lecturer	NYU-Stern School of Business, New York, New York Masters in Business Administration Program May 2009 - June 2011
Guest Lecturer	Iona University, Bronx, New York Masters in Healthcare Management Program Jun 2009 – 2013
Adjunct Professor	The School of Business at Adelphi University, Garden City, New York Masters in Business Administration Program Jul 2010 - Nov 2011
Professor of Clinical Medicine	Case Western Reserve University School of Medicine 2013 - Present

FACULTY & ACADEMIC APPOINTMENTS (Continued)

1989	National Board of Medical Examiners
1992	American Board of Internal Medicine (Non-renewed)
1992	American College of Physician Executives
2005	American College of Healthcare Executives
2007 - Present	Fellow, American College of Healthcare Executives

LICENSURE

1989 - Present	New York

ADMINISTRATIVE AND EXECUTIVE APPOINTMENTS

Aug 1992 - May 1997	Director, Medical Services Winthrop University Hospital, Mineola, New York
Jul 1993 - May 1997	Medical Director - Case Management Winthrop University Hospital, Mineola, New York
Jun 1994 - May 1997	Vice President Long Island Primary Medical Care, Inc., Garden City, New York
Jan 1995 - May 1997	President Family Practice Specialists, Hicksville, New York
Jul 1995 - May 1997	Associate Medical Director - Utilization and Quality Management Winthrop University Hospital, Mineola, New York
Jul 1995 - May 1997	Medical Director - Managed Care Winthrop University Hospital, Mineola, New York
May 1995 - Dec 1997	Board of Directors First Choice HMO, New York, New York
Jan 1996 - Jun 1997	Vice President Winthrop–South Nassau MSO, Inc., Garden City, New York
Jan 1996 - Jun 1997	President Winthrop Medical Staff IPA, Mineola, New York
May 1997 - Mar 1998	Vice President for Medical Affairs and Medical Director South Nassau Communities Hospital, Oceanside, New York

ADMINISTRATIVE AND EXECUTIVE APPOINTMENTS (Continued)

May 1997 - Jun 2005	Designated Institutional Officer, Graduate Medical Education South Nassau Communities Hospital, Oceanside, New York
Mar 1998 - May 2000	Vice President for Medical Affairs and Strategic Planning South Nassau Communities Hospital, Oceanside, New York
Jan 1999 - Marh 2007	Chair, Performance Improvement Steering Committee South Nassau Communities Hospital, Oceanside, New York
May 2000 - Jan 2003	Senior Vice President, Medical Affairs and Administration South Nassau Communities Hospital, Oceanside, New York
Mar 2001 - Mar 2007	President Long Island Gamma Knife, LLC, Oceanside, New York
Feb 2003 - Mar 2005	Executive Vice President and Chief Medical Officer South Nassau Communities Hospital, Oceanside, New York
Mar 2005 - Mar 2007	Executive Vice President, Chief Operating Officer & Chief Medical Officer South Nassau Communities Hospital, Oceanside, New York
Apr 2007 - Nov 2008	Executive Vice President and Chief Administrative Officer St. Francis Hospital - The Heart Center, Roslyn, New York
May 2008 - Nov 2008	Treasurer and Secretary St. Francis Cardiovascular Physicians, PC, Roslyn, New York
Dec 2008 - May 2010	Chief Medical Officer/Chief Academic Officer - Interim Saint Vincent Catholic Medical Centers, New York, New York
Jan 2009 - May 2013	Founder and President BusinessFirst Healthcare Solutions, Great Neck, New York
Feb 2009 – May 2013	President Patient Innovations, LLC, Hauppauge, New York
Apr 2009 - Mar 2013	Co-Founder and Principal MediMetrix Solutions Exchange-MX.com, Boca Raton, Florida
Sep 2009 - Sep 2010	Business Development & Physician Integration Advisor North Shore-LIJ Health System, Manhasset, New York
Dec 2011 - May 2012	Clinical Transformation Executive - Interim Brookdale University Hospital & Medical Center, Brooklyn, New York
May 2010 - Jan 2013	Chairman and Chief Executive Officer Wellspring Health Services, Centerport, New York

ADMINISTRATIVE AND EXECUTIVE APPOINTMENTS (Continued)

Jun 2013 – Nov 2022	President and Chief Executive Officer The MetroHealth System, Cleveland, Ohio
Feb 2023 – Present	Co-Founder and Chief Executive Officer Nightingale Bedside, LLC., Boca Raton, Florida

HOSPITAL/MEDICAL SCHOOL COMMITTEE MEMBERSHIP

1991 - 1995	Quality Assurance and Quality Improvement Committee, WUH
1991 - 1996	Chairman, Residency Selection and Promotions Committee, WUH
1992 - 1994	Chair, Patient & Family Education Committee, WUH
1993 - 1997	Chair, Case and Utilization Management Committee, WUH
1994 - 1995	Chairman, Primary Care Initiative Task Force, WUH
1997 - 2003	Chair, Utilization Management Committee, SNCH
1997 - 2007	Finance Committee of the Board of Directors, SNCH
1997 - 2007	Board of Directors, SNCH
1998 - 2006	Board of Directors, Winthrop-South Nassau University Health System
1998 - 2006	Finance Committee of the Board of Directors, WSNUHS
1998 - 2003	Strategic Planning Committee of the Board of Directors, WSNUHS
1998 - 2007	Chair, Medical Liability Committee, SNCH
1998 - 2002	Clinical Resource Management Committee, LIHN
2000 - 2004	Clinical Guideline Development & Best Practices Committee, LIHN
2000 - 2005	Laboratory & Transfusion Committee, SNCH
2001 - 2007	Chair, Managed Care Executive Committee, SNCH
2002 - 2007	Chair, Health System Long Range Planning Group, WSNUHS
2002 - 2007	Ethics Committee, SNCH
2003 - 2005	Chair, Peer Review Committee, SNCH
2003 - 2005	Chair, Strategic Planning Committee of the Board of Directors, WSNUHS
2003 - 2006	Quality Leadership Committee, Healthcare Association of New York State

HOSPITAL/MEDICAL SCHOOL COMMITTEE MEMBERSHIP (Continued)

2004 - 2007	Chair, Employee Engagement Committee, SNCH
2004 - 2007	Chair, High Potential Executive Development Program, SNCH
2005 - 2007	Chair, Institute for Healthcare Improvement Committee, SNCH
2005 - 2007	Chair, Patient Satisfaction Committee, SNCH
2006 - 2007	Chair, Innovation Center Committee, SNCH
2006 - 2008	COO Leadership Committee, Healthcare Association of New York State
2007 - 2008	Chair, CLAB-Zero (Central Line Infection) Committee
2009 - 2010	Chair, Risk Management Committee & Medical Liability, SVCMC

NATIONAL COMMITTEE MEMBERSHIP

2007 - 2008	Committee on Restructuring Regional Boards - American Heart Association
2007 - 2009	Alternate Delegate, American Hospital Association, Regional Policy Board-Region 2
2009 - 2012	Delegate, American Hospital Association, Regional Policy Board-Region 2
2012	Best-in-Class Programs for the Treatment of the Complex Chronically Ill - California Health Care Foundation
2012	Identifying and Stratifying Patients with Complex or Multiple Chronic Conditions (MCC) - U.S. Department of Health and Human Services
2012	New Models in Care - Health Plan Alliance

MAJOR TEACHING AND CLINICAL RESPONSIBILITIES

1992 - 1994	Assistant Program Director, Medicine Residency Program, WUH
1994 - 1996	Associate Program Director, Medicine Residency Program, WUH
1992 - 1996	Director, Morning Report, Department of Medicine, WUH
1992 - 1996	Outpatient Internal Medicine Clinic, WUH
1996 - 1997	Clinic Director, Outpatient Internal Medicine, WUH
1995 - 1999	

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MAJOR TEACHING AND CLINICAL RESPONSIBILITIES (Continued)

1992 - 1997	Faculty Attending, Winthrop University Hospital
1997 - 2007	Faculty Attending, South Nassau Communities Hospital

AWARDS, HONORS AND MEMBERSHIP IN HONORARY SOCIETIES

1982	Outstanding Leadership Award American Chemical Society
1987	Young Research Scientist Award (Discovery of mechanism of action of ranitidine) Glaxo Pharmaceuticals
1994	Finalist, Poster Competition (Study of resident work hours) American College of Physicians
2007	Master Physician Designation Nassau Academy of Medicine, and Nassau County Medical Society
2008	Cardiovascular Science Award (Advancement of cardiac care) American Heart Association
2008	Alumni Outstanding Achievement Medal Saint John's University
2008	Physician Hero Award (Achievements and contributions to healthcare) Long Island Business News
2009	David Award for Renaissance Men Networking Magazine
2009	Man of the Year New York RotaCare
2010	Knight of Merit, Sacred Military Constantine Order of Saint George The Vatican and Royal House of Bourbon
2012	ASC Leaders to Know Becker's ASC Review
2013	Clark-Curran Award in Medical Administration State University of New York - Downstate College of Medicine

INSTITUTIONAL SPONSORSHIP OF COMPETITIVE AWARDS

1996	Health Care Excellence Award, MMI, Inc. Winthrop University Hospital, Mineola, New York

2005	Pinnacle Award for Quality South Nassau Communities Hospital, Oceanside, New York
2007	Nation's Best Hospitals from U.S. News and World Reports St. Francis Hospital-The Heart Center, Roslyn, New York
2008	Nation's Best Hospitals from U.S. News and World Reports St. Francis Hospital-The Heart Center, Roslyn, New York
2008	Best Hospital on Long Island from Long Island Press St. Francis Hospital-The Heart Center, Roslyn, New York
2008	Summit Award from Press Ganey for outstanding patient satisfaction St. Francis Hospital-The Heart Center, Roslyn, New York

MEMBERSHIPS IN PROFESSIONAL AND SCIENTIFIC SOCIETIES

National Societies	American Hospital Association Regional Board (Former Member)
	American Essential Hospital Board (Former Member)
	Vizient Board (Former Member)
	Health Industry Solutions Forum (Chair)
	American College of Healthcare Executives (Fellow)
	National Quality Forum (Former Member)
	American College of Physicians (Former Member)
	Creative Collaboration for Hospital Executives (Member)
	Healthcare Performance Metrics (Member)
	American College of Physician Executives (Member)
	American Medical Association (Member)
	Association of Program Directors in Internal Medicine (Former Member)
	Society for General Internal Medicine (Former Member)
Local Societies	Health Leaders of New York (Member)
	COO Leadership Committee, HANYS (Former Member)
	Quality Leadership Committee, HANYS (Former Member)
	New York Academy of Medicine (Former Member)
	Nassau County Medical Society (Former Member)
	New York State Society of Internal Medicine (Former Member)

CIVIC ORGANIZATIONS

2003 - 2005	Board of Advisors - NYS Office for Minority Health, Hempstead, NY
2005 - 2008	Board of Directors - Helen Keller Services for the Blind, Brooklyn, NY
2007 - 2010	Board of Directors - American Heart Association, Long Island Chapter
2007 - 2008	Vice President, BoD - American Heart Association, Long Island Chapter
2008 - 2010	President, BoD - American Heart Association, Long Island Chapter
2009 - 2011	Board of Trustees - St. Dominic High School, Oyster Bay, New York
2010 - 2011	Co-Chair, 46th Annual Heart Ball - American Heart Association,
2013 - 2014	Chair, Board of Trustees - St. Dominic High School, Oyster Bay, New York
2013 – 2022	Board Member – Greater Cleveland Partnership
2015 – 2019	Board Member – United Way of Greater Cleveland
2016 – 2020	Board Member – Cuyahoga Community College Foundation
2016 – 2022	Chair, Board of Directors – Select Assurance of Ohio
2017 – 2020	Chair, Board of Directors – Lobesity Pharmaceuticals
2017 – 2021	Chair, Board of Directors – First Year Cleveland
2017 – 2022	Chair, Board of Directors - CCH Developmeny Corporation
2019 – 2020	Board Member - BioEnterprises
2019 – Present	Board Member – Destination Cleveland

HEARINGS AND TESTIMONY

2001	Acute Angioplasty at Non-Surgical Site Hospitals Cardiac Advisory Committee, Albany, New York
2005	Elective Angioplasty at Non-Surgical Site Hospitals Cardiac Advisory Committee, Albany, New York
2006	Commission on Health Care Facilities in the 21st Century New York State Department of Heath, Garden City, New York

HONORS

2016	Honorary Doctorate of Humanities - Northeast Ohio Medical University
2019	Honorary Doctorate of Public Service – Baldwin Wallace University

AWARDS

2015	EY Entrepreneur of the Year – Community Impact, Northeast Ohio
2016	Sam Miller Goodness Award – Values in Action Foundation
2017	Stokes Community Leadership Award
2018	Richard H. Adler Community Leadership Award – American Jewish Federation
2018	George V. Voinovich Municipal Service Award – Cuyahoga County Mayors & Managers
2019	Crains Cleveland - CEO of the Year Award
2019	Humanitarian Award – The Diversity Center of Northeast Ohio
2020	Becker's Healthcare Leadership Award – Becker's Hospital Review
2021	Modern Healthcare's 50 Most Influential Clinical Executives
2021	Global Cleveland's Albert B. & Audrey Ratner Community Leader Award
2022	Collaborative Champion Award – Better Health Partnership
2022	Maurice Saltzman Award – Mount Sinai Healthcare Foundation
2022	Arnold R. Pinkney Award for Civiv Leadership – Values in Action Foundation

EXHIBIT C

COVID-19 Vaccine Religious Exemption

	A	B	C	D	E	F	G	H
1	Date Reviewed	EE Number	Employee Name	Dept or Location/Entity	Job Title	Decision YES	Decision NO	Notes:

REDACTED

REDACTED

A	B	C	D	E	F	G	H

REDACTED

COVID-19 Vaccine Religious Exemption

	A	B	C	D	E	F	G	H

REDACTED

	A	B	C	D	E	F	G	H
	REDACTED							
156	9/17/21	11308	Gray, Dawn	PH: Emergency Room	Clinical Coordinator		X	Does not state or articulate a comprehensive, a long-standing, deeply held belief about ultimate ideas about life, purpose or death. Focused on medical information - fertility
	REDACTED							

	A	B	C	D	E	F	G	H

REDACTED

COVID-19 Vaccine Religious Exemption

	A	B	C	D	E	F	G	H	I	J	K
1	Original Date Reviewed	EE Number	Employee Name	Dept or Location/Entity	Job Title	Decision YES	Decision NO	communicated to EE	Appeal Requested	Appeal Notes	Appeal Decision

REDACTED

COVID-19 Vaccine Religious Exemption

	A	B	C	D	E	F	G	H	I	J	K

REDACTED

62	9/17/21	11308	Gray, Dawn	PH: Emergency Room	Clinical Coordinator		X	9/23/21	YES		upheld

REDACTED

	A	B	C	D	E	F	G	H	I	J	K

REDACTED

REDACTED

REDACTED

EXHIBIT D

Religious Exemption

Denial:

NOTE: USE ONE OR MORE AS APPLICABLE

Citing medical reason to object to vaccination instead of a sincerely held religious/spiritual belief to support an exemption. (NOTE: used to deny when information is accurate – just don't like it)

Citing false/inaccurate medical or scientific information about the vaccine to object to vaccination instead of a sincerely held religious/spiritual belief to support an exemption. (NOTE: use to deny when information is inaccurate.)

Does not state or articulate a comprehensive, a long-standing, deeply held belief about ultimate ideas about life, purpose or death.

Applicant simply provides a litany of scripture quotes that do not articulate a sincerely held comprehensive religious belief and that is not relevant to exemption request process.

Stated beliefs are inconsistent with current or previous vaccination or medical treatment and/or practices.

Applicant's statement does not attest to any personal sincerely held religious or spiritual belief system.

Applicant's statement does not establish their beliefs are long-standing, that request is consistent with other life behaviors and practices.

Applicant's statement cites political and/or social commentary as a rationale to support a request for vaccine exemption based on a sincerely held religious belief. NOTE: This may be in addition to scientific misinformation which can also be added.

Applicant utilizes form documents from outside political or religious organizations citing political or social or scientific rationales rather than any personal sincerely held religious belief to support request for religious exemption.

Applicant submitted form letter from a resourced (internet) religious organization to attempt to attest to personal sincerely held religious belief.

Accepted:

Belongs to a faith tradition, religious denomination, or philosophical understanding that does not permit vaccines.

Belongs to a faith tradition, religious denomination, or philosophical understanding that does not permit vaccines derived from or tested on fetal cell lines.

Belongs to a faith tradition, religious denomination, or philosophical understanding that does not permit any medical intervention.

Personal spiritual/religious/philosophical beliefs around vaccines and use of fetal cell line testing. Belief is sincerely held. Long-standing. Consistent with other practices.

Personal spiritual/religious/philosophical beliefs around use of medical interventions interfering with ultimate purpose/plan/higher power. Belief is sincerely held. Long-standing. Consistent with other practices.